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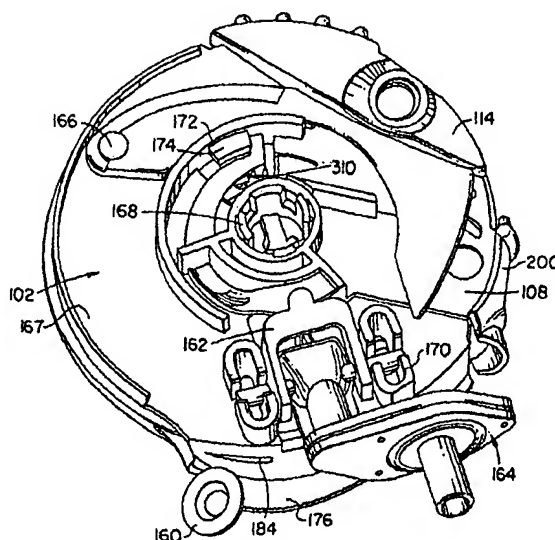
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[Continued on next page]

(54) Title: **DRY POWDER INHALER**



(57) Abstract: A dry powder inhaler (100) including a blister disk (105) and an actuator/dobber (152/162) pivotably mounted on a base and a tray retainer (114), a dispersion engine (164) with a hood (234) over a blister opening position. A powder pathway (118) interconnects the hood to the engine. Inhalation draws powder from a blister and into the hood and engine. A blister tray assembly (104) includes a blister disk pivotably supported on a mounting hub (301). A lockout ratchet (310) is spring biased and engages the blister disk to prevent movement. Reverse movement of the actuator disengages the lockout ratchet and permits incremental movement of the blister disk by one position.

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## S P E C I F I C A T I O N

DRY POWDER INHALERBACKGROUND OF THE INVENTION

5 [0001] Inhalers are used to deliver drugs into a patient's lungs. Typically, an inhaler contains or provides a mixture of drug particles and air or propellant gas. The mixture is delivered via the patient inhaling from a mouthpiece on the inhaler with the air or propellant gas carrying the drug particles into the patient's lungs.

[0002] In dry powder inhalers, the drug particles, in the form of a fine dry  
10 powder, are entrained into an airflow, and inhaled by the patient, for treatment for various conditions, for example, bronchial asthma. Drugs delivered via a dry powder inhaler can be used to treat many conditions, including those unrelated to lung conditions, via the systemic absorption of the drug into the bloodstream, via the lung.

[0003] For effective dose delivery using a dry powder inhaler, the powder  
15 particles must first be dispersed to form a powder/air aerosol. Various techniques for forming powder aerosols have been proposed. Some of these techniques use the airflow from the patient's inspiration alone to disperse the powder. Other techniques involve forming a powder aerosol by spinning a propeller within a chamber; generating a fast moving flow of air over or through the powder; and shaking, vibrating, or impacting a  
20 powder laden string, tape, or mesh, using mechanical devices or ultrasonics. In addition, various other techniques for generating powder aerosols have been proposed or used, with varying degrees of success. Challenges remain in achieving a dry powder inhaler which can effectively create a dry powder aerosol for inhalation, while also

having advantages in other areas, such as effectiveness in creating an aerosol, reliability, complexity of design, costs, ergonomics, dose consistency, and other factors.

[0004] Dry powder inhalers have certain advantages over metered dose inhalers and nebulizers or liquid droplet inhalers. Typically, dry powder inhalers do not require propellant gases, which may be damaging to the environment. Dry powder inhalers generally also do not require a high level of user coordination between releasing a dose and inhaling the dose. As they do not release a burst or high speed plume of drug particles, having the release of the dose occur near simultaneously with inhalation is not required. Dry powder inhalers can also have relatively reliable and inexpensive designs.

10 [0005] Various techniques have been proposed for storing doses of powder in a dry powder inhaler. These techniques include bulk storage of the powder in a reservoir having a metering out device, gelatin capsules which are pierced or cut open, or blister disks having individual blisters which are punctured or sheared open. To better seal the pharmaceutical powder from the environment (to reduce caking, contamination, or other undesirable changes), individually sealed dose containers such as blister disks, are preferred. Inhalers using blister disks have had different ways of advancing the blister disk to deliver sequential doses, of opening the blisters, and of moving the powder out of the open blister for inhalation by the user. While test results on some of these types of inhalers have been promising, engineering challenges remain in providing reliable and accurate blister disk operations in a dry powder inhaler, while also providing advantageous human factors features.

20 [0006] Accordingly, it is an object of the invention to provide an improved dry powder inhaler.

STATEMENT OF THE INVENTION

[0007] Concepts of the invention include: pivotal movement of an actuator used for opening a blister; an actuator that moves into a position blocking movement of  
5 a retainer, to prevent installation of a blister disk unless the actuator is at or near its home position; use of a blister disk with the blister facing up, so that air flow draws powder up and out of the blister; an anti-double dose system using an up-facing blister, where the powder remains in the open blister, and is not moved into a dispersion or other chamber, until inhalation by the user; a blister hood which can be displaced into  
10 contact with a blister disk during inhalation, and spaced apart from the blister disk to allow the blister disk to advance one position.

[0008] In a first aspect, an inhaler for providing multiple doses of a pharmaceutical powder from blisters on a blister disk includes an actuator pivotably mounted on a base. The actuator preferably includes a ramp. A dobber or plunger is  
15 engaged with the ramp on the actuator. Movement of the actuator from a first position to a second position causes the ramp to drive the dobber to open a blister.

[0009] In a second aspect, the base includes a tray retainer moveable between opened and closed positions, and with the actuator moveable to a position at least partially overlying the tray retainer, when the tray retainer is in the closed position.

20 [0010] In a third aspect, the tray retainer is moveable from a closed position, wherein it secures a blister disk tray assembly onto a first side of the base. The tray retainer is also moveable to an open position, where it is spaced apart from the base, to allow removal and replacement of the blister disk tray assembly.

[0011] In a fourth aspect, an inhaler includes a blister hood positioned over a blister opening position. A powder pathway connects from the blister hood into a powder dispersion engine in the inhaler. Upon inhalation, air flow draws powder up and out of an opened blister, into the blister hood and to the powder dispersion engine.

5 [0012] In a fifth aspect, the powder dispersion engine includes an engine tube having inwardly projecting ribs acting as an air flow restriction.

[0013] In a sixth aspect, the dobber is positioned so that movement of the actuator causes the dobber to shear open a blister on a blister disk, and also to press the blister hood down over, or into contact with blister disk. Upon inhalation, an increased  
10 amount of air flows up and around the open blister, carrying the pharmaceutical powder up and out of the blister and into the dispersion engine.

[0014] In a seventh and separate aspect, a dust cap is attached to the inhaler housing with a hinge oriented at an acute angle to the housing.

[0015] In a method for operating a dry powder inhaler, a tray holding a blister  
15 disk is installed into the inhaler. An actuator is pivoted in a first direction to open a blister on the blister disk. Upon inhalation, the pharmaceutical powder is conducted up and out of the open blister and into a dispersion engine, via inhalation air flow. The powder is dispersed in air in the dispersion engine. The actuator is pivoted back in the reverse direction, to advance the blister disk in the tray.

20 [0016] A blister disk tray assembly for use with a dry powder inhaler includes a blister disk pivotably supported on a mounting hub. A lock out ratchet is spring biased into engagement with the blister disk, preventing any pivotal movement of the blister disk. When used in an inhaler, returning movement of an actuator in the inhaler

momentarily disengages the lock out ratchet from the blister disk, allowing the actuator to incrementally advance the blister disk by one position, to bring a subsequent blister into position for opening.

[0017] Other and further aspects and advantages will appear in the following  
5 detailed description taken in connection with accompanying drawings. While a single embodiment is shown and described, the drawings and description are intended to provide an overview of the general concepts of the inventions. Various alternative designs and equivalents may of course be used.

[0018] The invention also contemplates sub-combinations of the various  
10 components, subassemblies and method steps described. The various aspects described above need not all necessarily be included in the invention. Rather they can generally be used independently, or in various combinations and sub-combinations.

#### BRIEF DESCRIPTION OF THE DRAWINGS

15 [0019] In the drawings, wherein the same element number represents the same element, throughout the several views:

[0020] Figure 1 is a top perspective view of a novel dry powder inhaler, shown in the stored position.

[0021] Figure 2 is a bottom view of the inhaler of Figure 1.

20 [0022] Figure 3 is a right side view of the inhaler of Figure 1.

[0023] Figure 4 is a front view of the inhaler of Figure 1, with the dust cap shown in the closed position.

- [0024] Figure 5 is a front view of the inhaler of Figure 1, with the dust cap shown in an open position.
- [0025] Figure 6 is a top perspective view of the dust cap shown in Figures 4 and 5.
- 5 [0026] Figure 7 is a rear view of the dust cap shown in Figure 6.
- [0027] Figure 8 is a top perspective view of the top cover of the inhaler shown in Figure 1.
- [0028] Figure 9 is a bottom perspective view of the cover shown in Figure 8.
- [0029] Figure 10 is a right side view of the cover shown in Figures 8 and 9.
- 10 [0030] Figure 11 is a front perspective view of the mouth piece on the inhaler shown in Figure 5.
- [0031] Figure 12 is a rear perspective view of the mouth piece of Figure 11.
- [0032] Figure 13 is a top and front perspective view of the inhaler shown in Figure 1, with the top cover shown in Figure 8 removed.
- 15 [0033] Figure 14 is a top and front perspective view of the base plate shown in Figure 13.
- [0034] Figure 15 is a bottom and rear perspective view of the base plate of Figure 14.
- [0035] Figure 16 is a right side view of the base plate shown in Figure 14.
- 20 [0036] Figure 17 is a top view of the blister disk tray latch shown in Figures 1, 3 and 13.
- [0037] Figure 18 is a top perspective view of the latch of Figure 17.
- [0038] Figure 19 is a right side view of the latch of Figure 17.

[0039] Figure 20 is a top and left perspective view of the actuator shown in Figure 13.

[0040] Figure 21 is a top view of the actuator of Figure 20.

[0041] Figure 22 is a top and left side perspective view of the actuator of Figure  
5 20.

[0042] Figure 23 is a top perspective view of the dispersion engine shown in Figure 13.

[0043] Figure 24 is a bottom perspective view of the dispersion engine shown in Figure 23.

10 [0044] Figure 25 is a top and rear perspective view of the dispersion engine back.

[0045] Figure 26 is a front perspective view of the engine back of Figure 25.

[0046] Figure 27 is a rear perspective view of the engine front shown in Figure 23.

15 [0047] Figure 28 is a section view of the dispersion engine shown in Figure 23, and taken along line 28-28 of Figure 23.

[0048] Figure 29 is an enlarged detail of the left side of Figure 28.

[0049] Figure 30 is a bottom perspective view of the dobber shown in Figure 13.

[0050] Figure 31 is a top perspective view of the blister disk tray assembly  
20 shown in Figure 2.

[0051] Figure 32 is a side view of the dispersion engine of Figure 23 and the blister disk of the blister disk tray assembly shown in Figure 31.

[0052] Figure 33 is a bottom view of the blister disk tray shown in Figure 31.

[0053] Figure 34A is a top and front perspective view of the blister disk tray shown in Figures 2, 31, and 33.

[0054] Figure 34B is an enlarged front view of the ratchet lock shown in Figure 34A.

5 [0055] Figure 35 is a right side view of the blister disk tray shown in Figure 34.

[0056] Figure 36 is a bottom and side perspective view of the blister disk tray spring shown in Figure 31.

[0057] Figure 37 is a partial top perspective view of the inhaler of Figure 1, with the blister disk tray assembly removed and with the tray spring of Figure 36 shown in  
10 position, for clarity of illustration.

[0058] Figure 38 is an exploded perspective view of the blister disk shown in Figure 31 and 32.

[0059] Figure 39 is a top view of the blister disk shown in Figure 38.

[0060] Figure 40 is a section view taken along line 40-40 of Figure 39.

15 [0061] Figure 41 is a top view of the inhaler of Figure 1 with the blister disk tray latch in the open position.

[0062] Figure 42 is a bottom view of the inhaler as shown in Figure 41, with the blister disk tray assembly of Figure 31 removed.

[0063] Figure 43 is an enlarged detail of the latch shown in Figure 42.

20 [0064] Figure 44 is a top and front perspective view of the inhaler of Figure 1, with the dust cap open and the actuator in the home or stored position.

[0065] Figure 45 is a top and front perspective view of the inhaler of Figure 44 with the actuator moving towards an inhale position.

[0066] Figure 46 is a top and front perspective view of the inhaler of Figure 44, with the actuator moved fully into the inhale position.

#### DETAILED DESCRIPTION

5 [0067] Turning now in detail to the drawings, as shown in Figures 1-4, an inhaler 100 has a mouthpiece frame 176 on a base or base plate 102. A dust cap 112 is pivotably secured to the base plate 102 via an angled hinge 115. A blister disk tray assembly 104 is attached or engaged to the bottom surface of the base plate 102. A tray retainer 114 secures the tray assembly 104 in place on the base plate 102. An actuator  
10 108 is pivotably moveable over a sector of about 50-80 or 60-70 degrees to actuate the inhaler 100. A top cover 130 is attached over the top surface of the base plate 102.

[0068] As shown in Figures 4-7, the hinge assembly 115 includes a hinge plate 118 on the dust cap 112 secured between a hinge top 134 on the top cover 130 and a hinge bottom 160 on the base plate 102. The hinge plate 118 is oriented at an acute  
15 angle AN of 15-45°, 20-40°, 25-35° or 30° relative to the dust cap horizontal axis H-H. The axis H-H is parallel to the plane (the flat top or bottom surfaces) of the base plate 102. In use, the inhaler 100 is held with axis H-H horizontal or near horizontal (perpendicular to gravity). Axles 118 and 120 on the hinge plate extend into and are pivotably secured by the hinge bottom 160 and hinge top 134. A mouthpiece 110,  
20 shown in Figures 11 and 12, is attached to the mouthpiece frame 176 on the base plate 102. As shown in Figure 5, when the dust cap 112 is pivoted to the open position, the dust cap moves both down and away from the mouthpiece 110. This provides added

clearance around the mouthpiece. Hence, the dust cap does not interfere with use of the inhaler.

[0069] Turning to Figures 8-10, the top cover 130 has upper dobber supports 136 near the front and generally opposite to a back edge 132. A cover hub 138 is generally centrally located on the bottom surface of the cover 130. The hinge top 134 is attached to a front wall 137 of the cover 130, generally at an angle AN to the plane of the cover.

[0070] Turning to Figures 11 and 12, the mouthpiece 110 has a stem 142 on a rear cup or base 146. A mouthpiece tube 144 extends through the stem 142. A notch 148 at the left end of the cup 146 provides clearance for the hinge assembly 115, when the inhaler components are assembled. The stem 142 is smoothly contoured. In use, the users lips may be comfortably placed around the stem. Referring momentarily to Figure 5, the stem 142 is offset to the right side of the inhaler. This provides additional clearance between the stem 142 and the dust cap 112, when the inhaler is in use.

[0071] Turning now to Figure 13, which shows internal components of the inhaler 100, the actuator 152 is pivotably attached to a central hub 168 on the top surface 167 of the base plate 102. A powder dispersion engine 164 is attached to the front of the base plate 102. The tray retainer 114 is pivotably attached to a pin 166 on the top surface of the base plate 102. A dobber 162 is pivotably supported on the base plate 102 adjacent to the dispersion engine 164. As described in detail below, in use, the actuator drives the dobber to open a blister on a blister disk in the blister disk tray assembly 104.

[0072] The base plate 102 is shown in detail in Figures 14-16. The mouthpiece frame 176 is attached to and extends down from the bottom surface 169 of the generally circular base plate 102. A dobber opening 178 extends through the base plate 102 between the mouthpiece frame 176 and the hub 168, which is generally centered on the base plate 102. Openings 171 are provided around the hub 168 to better facilitate manufacture. A dose indicator base plate window 180 extends through the base plate 162. A ramp 172 on the top surface of the base plate 102 cooperates with the actuator 108, as described below.

[0073] As shown in Figures 17-19, the tray retainer 114 has an opening 191 at the end of a pivot arm 190 which is pivotably attached onto the pin 166 on the base plate 102. A finger grip 192 on the pivot arm 190 has a window 194 and an inward facing tray tooth 198. The inner edge 196 of the finger grip 192 is contoured to match the back edge 132 of the cover 130, as shown in Figure 1. The curved inside surface 193 of the pivot arm 190 generally conforms to the radius of the ramp 172 on the base plate 102. The retainer 114 may be replaced with various equivalents such as latches, snaps, gates and similar devices. The term "retainer" in the claims means a component or feature that helps to hold the blister disk (or other drug carrier) onto the inhaler.

[0074] Referring to Figures 20-22, the actuator 108 has a curved finger plate 200 attached to an arm 202 connecting to a hub opening 206. A ramp flange 212 extends partially around the hub 206. An advancing finger 208 is attached to the ramp flange. A blister disk engaging tooth 210 on the advancing finger 208 advances a blister disk in the tray assembly 104 with movement of the actuator. A movement indicator 204 attached to the arm 202 has first and second windows 222 and 224, and arrows 226

which help provide visual operating instructions to the user. The ramp flange 212 has a center section 213 having a compound curvature, bounded by a flat start section 214 and a flat end section 216. The center section curves both vertically and horizontally, like an involute screw thread, to better engage with the dobber 162 over the range of movement  
5 of the actuator 108. The actuator may have various forms. The term "actuator" in the claims means a component or feature that the user moves, directly or indirectly, to open a blister (or other drug container).

[0075] Referring momentarily to Figure 30, the dobber 162 has first and second legs formed in a U-frame 276. Axle stubs 286 extend outwardly on each of the legs of  
10 the U-frame. A cam tooth 228 extends downwardly from a tooth plate 280 on the U-frame. An actuator plate 282 is spaced apart from the tooth plate 280. The ramp flange 212 of the actuator 108 fits into the slot 284 formed between the tooth plate 280 and the actuator plate 282, when the components are assembled. The term "dobber" means a component or feature moved directly or indirectly by an actuator, for opening a  
15 blister or other drug container.

[0076] Pivotal movement of the actuator 108 consequently drives the dobber to pivot about the axle stubs 286, to shear open a blister on the blister disk. The dobber supports 136 on the underside of the top cover engage the axle stubs, and hold them in place from above, along with the supports 170 on the base plate 102, which engage and  
20 hold the axle stubs from below.

[0077] Turning now to Figures 24-27, an engine back 232 has a back bead race 246 formed within a chamber back plate 235. Attachment pins 244 extend forward from the back plate 235. A blister hood 234 is formed on a hood plate 236 attached generally

perpendicularly to the back plate 235. A hood chamber 240 is formed within the blister hood. A hood duct 242 extends through the blister hood and connects with an inlet 248 on the front surface of the engine back 232. A back inlet recess 249 extends from the inlet 248 to the back race 246. Grooves 238 may be provided in the hood plate 236 to  
5 adjust its bending characteristics.

[0078] Referring to Figure 27, an engine front plate 230 has a front bead race 262 surrounding a chamber outlet 254, and matching the size and shape of the back bead race 246 in the engine back 232. The chamber outlet 254 connects into an engine tube 258 extending forward from the engine front 230. Pin openings 256 are positioned and  
10 adapted to mate with the attachment pins 244 on the engine back 232. A front inlet recess 260 in the back surface of the engine front plate connects in the back bead race 246 and is formed as a mirror image of the inlet recess 249 in the engine back 232.

[0079] Referring now to 23, 24, and 27-29, the powder dispersion engine 164 is formed by the combination of the engine back 232 and the engine front 230. The  
15 attachment pins 244 pass through the pin openings 256 to secure the engine back and engine front together. The back race 246 aligns with the front race 262 and forms a bead chamber 250. Beads 264 are provided in the bead chamber 250, before assembly, as described in International Patent Application PCT/US01/03248. The term "beads" means one or more objects which can move freely within the dispersion chamber to  
20 disperse powder. While the above-described dispersion engine 164 is preferred, other dispersion techniques may also be used, including for example, engines without beads or any moving parts, engines having fixed or moving, powered or free spinning vanes or

propellers, engines using compressed gases, electrostatic vibratory, piezo electric, or other techniques.

[0080] Referring to Figures 28 and 29, when the engine back 232 is attached to the engine front 230, a lip ring 266 on the engine front engages into a raised area 249 on the engine back, to better close off or seal the bead chamber 250 (except at the inlet and engine tube 258). As shown in Figure 28, ribs 268 extend radially into the engine tube 258. The ribs form a restriction in the tube, which accelerates flow during inhalation. As shown in Figure 5, when assembled, the engine tube 258 extends concentrically through the tube 144 in the mouthpiece 110.

10 [0081] Turning now to Figures 31 and 33-35, the tray assembly 104 is made up of a tray 290 and a blister disk 106. The tray has a front wall 295 adapted to engage with the back side of the mouthpiece frame 176. Tabs 314 on the front wall 295 extend into corresponding slots 184 on the back surface of the mouthpiece frame 176, as shown in Figure 37.

15 [0082] Referring to Figure 34, the blister disk 106 is pivotably attached to a post 300 located generally at the center of the generally round tray 290. The post 300 preferably has locking spring arms 301 or other permanent fastener, to prevent separation of the blister disk 106 from the tray 290. A lockout arm 310 extends upwardly and engages a spoke 365 of the blister disk 106, to prevent pivoting or turning movement of the blister disk 106, in either direction (clockwise or counter clockwise),  
20 when the tray assembly 104 is separated from the inhaler 100. The lockout arm 310 is momentarily depressed by the actuator to allow for incremental advancing movement of the blister disk 104.

[0083] A blister tab base wall 308 extends around the tray 290, except at the blister opening position 309. The base wall 308 helps to maintain the tabs of the blister disk 106 in a flat or planar position as the disk 106 incrementally pivots within the tray during use, especially after the tabs are actuated to release a dose of powder. A first  
5 outer wall 304 supports the perimeter of the blister disk 106.

[0084] As shown in Figures 36 and 37, a return spring 316 has a clip section 318 which attaches to the front wall 295 of the tray 290, with an arm section 320 of the spring extending into the blister opening position 309. The arm section 320 of the return spring 316 acts to return the tabs of the blister disk 106 to their starting position,  
10 after the tab is actuated to release a dose of powder from a blister.

[0085] As shown in Figure 33, the bottom surface of the tray 290 has feet 292 and 294, to allow the tray 290 to rest on a flat surface without tipping or rocking. An opening 312 under the ratchet lock, facilitates manufacturing by injection molding. A label recess 298 is provided around the opening 312.

[0086] Turning now to Figures 31 and 38-40, the blister disk 106 preferably includes a hard plastic base disk 364, and a metal foil shear layer 362 and a blister layer 360. Blisters 356 containing a pharmaceutical powder 358 are formed in the blister layer 360. The shear layer 362 is adhered to the blister layer 360 and to the disk 364. The disk 106 includes a plurality of tabs 352 equally radially spaced apart and supported  
15 on pivot arms 354. Each of the tabs 352 can pivot within a cutout 366 in the base disk 364, by an amount sufficient to open the shear layer 362 and release the powder 358 in the blister 356. Tab openings 366 around each of the tabs 352 are separated by spokes 365. The bottom surface of each spoke is formed with an acute angle or a radius, to  
20

allow for more secure engagement of each spoke by the ratchet lock 310 on the tray 290. A center mounting hole 350 in the base disk 364 fits over the post 300 on the tray 290. The details of the blister disk 106 are described in International Patent Publication WO 96/33759. In use, in the inhaler 100, the bottom or blister side of the disk is facing  
5 down, while the tab side of the blister disk, shown in Figure 39 face up towards the base plate 102. As shown in Figure 32, the blisters open "up," i.e., the shear layer forms the top of the sealed blister compartments.

[0087] Operation of the inhaler is now described. To install or replace the tray assembly 104, the tray retainer 114 is pivoted outwardly about the retainer pivot post  
10 166. Referring to Figures 41-43, the actuator 108 is in the home or stored position. The tray assembly 104, as shown in Figure 31, is removed from its packaging and is installed onto the inhaler 100. Specifically, the front wall 295 of the tray 290 is positioned against the back wall of the mouthpiece frame 176. Referring momentarily to Figures 15, 34 and 37, the guide tabs 314 extending forwardly from the front wall 295  
15 of the tray 290 are inserted into the tab slots 184 on the back wall of the mouthpiece frame 176. The tray 310 is then moved into contact with, and sits substantially flush against the base plate 102. The tray retainer 114 is then pivoted inwardly, to secure the tray assembly 104 in place. The retainer tooth 198 shown in Figure 18 snaps into the indent 296 at the back of the tray 290, to secure the tray assembly 104 in place. The  
20 inhaler 100 then appears as shown in Figure 1, i.e., with a tray assembly 104 installed, and with the tray retainer 114 and actuator 108 in the home positions. The tabs 314 and slots 184 can be keyed so that only tray assemblies 104 having a specified pharmaceutical, can be installed onto the inhaler.

[0088] Referring to Figures 13, 34A, 34B and 39, when the tray assembly 104 is separated from the inhaler 100, the lockout ratchet 310 is constantly in an up position engaged around one of the spokes 365 of the blister disk 106, preventing any pivotal movement of the blister disk 106. This prevents inadvertent advancing of the blister disk within the tray (in either direction) which could result in loss of the ability to access doses in skipped blisters, or actuation of a blister which was previously accessed, resulting in no dose delivered. Even with the tray assembly 104 attached to the inhaler, the lockout ratchet 310 remains constantly engaged on one of the spokes 365, to prevent pivotal movement of the blister disk 106, except at the moment when the actuator is returned to the home position, as described below. The ratchet lock has a y-shaped slot 367 having a lower section with straight sidewalls 368 and an upper section with angled sidewalls 370. When engaged, a spoke 365 of the blister disk is positioned at least part way between the straight sidewalls.

[0089] Referring to Figures 44-46, the user pivots the dust cap 112 open. To open a blister and deliver a dose of powder, with the inhaler near horizontal, the user pushes or slides the actuator 108 from the stored position AA in Figure 44, to the inhale position CC shown in Figure 46. This causes the finger plate 200 of the actuator 108 to move over the tray retainer 114.

[0090] Referring to Figures 13 and 44-46, as the finger plate 200 is pushed from the home or stored position AA to the inhale position CC, the actuator 108 pivots circumferentially about the central hub 168. The advancing tooth 210 and finger 208 ride up and over the guide 174. The ramp flange 212 of the actuator pivots the dobber 162 about the axle stubs 286. The cam tooth 278 on the dobber 162 presses down on

the inner section 355 of the tab 352 located at the blister opening position 309. The blister tab 352 pivots on the pivot arms 354, shearing open the blister 356. The dose is then ready to be inhaled.

[0091] The patient places the stem 142 of the mouthpiece 110 into the mouth  
5 and inhales. Air is drawn through the inhaler 100, over the now open blister 356 into the hood chamber 240, through the inlet 242 and into the bead chamber 250 of the dispersion engine 164. The blister hood 234 is positioned directly over the (opened) blister at the blister opening position 309.

[0092] As the dobber 162 moves down to pivot the blister tab 352 to open a  
10 blister, the arm 320 of the return spring 316 is pushed down by the bottom surface of the blister tab 352. The dobber 162 also presses the blister hood 234 down slightly, as the dobber reaches the limit of pivoting movement. This causes the blister hood 234 to flex downwardly and contact the blister disk. The space or gap GG between the blister hood 234 and the disk 106, shown in Figure 32, is closed. Consequently air flow into the  
15 blister hood is confined to space over the open blister. As a result, powder from the blister is more efficiently lifted out and entrained in the air stream. When the actuator is reversed, the dobber lifts up and the blister hood separates from the blister disk, allowing the blister disk to advance. The hood plate 236 has sufficient flexibility to allow for this movement of the hood (typically about 0.1 - 0.3 mm).

20 [0093] The end sections 214 and 216 of the ramp flange 226 are flat, so as to not create any further travel of the dobber 120 near the limits of travel. This allows the actuator 108 to change direction more easily.

[0094] The geometry of the interaction between the dobber 162 and the blister tab 352 on the blister disk 106 is set up so that during initial contact, the cam tooth 278 on the dobber contacts the inside tip of the tab. This provides added leverage for shearing open the blister. As the blister tab 352 begins to pivot, the cam tooth 244  
5 moves inwardly, closer to the pivot arms 354, providing increased pivoting movement of the tab relative to the movement of the dobber. With this design, and the design of the ramp flange, the interaction between the dobber and the blister tab provides increased leverage and force at the beginning of movement, to shear open the blister, followed by decreased force, but increased travel, after shearing of the shear layer 362  
10 has commenced.

[0095] As the user inhales on the mouthpiece, air flows over and around the opened blister 356. The powder in the blister 356 is entrained into the air flow. The air/powder mixture flows up into the blister hood 234, through the inlet 242 and into the bead chamber 250. The bead(s) 264 in the bead chamber move about at high speed  
15 within the chamber. This disburses powder and also helps to separate active drug particles from inert carrier particles, as described in International Patent Application PCT/US01/03248. The disbursed powder and air flows out through the engine tube 258 and is inhaled by the user.

[0096] Referring to Figure 5, sheath air simultaneously flows out through an  
20 annular gap 259 between the engine tube 258 and the mouthpiece tube 144. The sheath air is drawn in from the sides of the mouthpiece 110 and contains no powder. Consequently, the powder laden air exiting the engine tube 258 is largely surrounded by sheath air. This helps to reduce settlement or deposition of drug particles on or in the

mouthpiece 110 and potentially also reduces deposition on the user's lips, mouth or throat.

[0097] After the user inhales the dose, the actuator 108 is returned to the home position AA as shown in Figure 44. As this occurs, the ramp flange 212 pivots the  
5 dobber 162 back into its horizontal or home position. The arm 320 of the return spring 316 pushes the blister tab 352 back into a horizontal position. The tooth flange 211 on the advancing finger 208 of the actuator 108 moves down under the guide 174 (shown in Figure 13) and through the actuator opening 182 in the base plate 102. The tooth flange 211 then pushes the ratchet lockout 310 down. The spoke 365 is then positioned  
10 between the angled sidewalls 370 of the y-slot 367 in the ratchet lock 310. The tooth 210 moves into a cutout 366 in the blister disk 106, and pivots the blister disk by one blister position. As the disk begins to move, the spoke 365 pushes the ratchet lock down further, by riding up and over the angled slot walls 370. The ratchet lock 310 then springs back up to engage around the next spoke. The inhaler 100 is then ready to  
15 deliver a subsequent dose. As shown in Figures 13 and 34A, the ratchet lock 310 extends up and in or across the tray 290 (as a horizontal chord), from the left or leading side of the tray. In these Figures, showing the inhaler and tray as viewed from above, the disk indexes clockwise. Consequently as the disk indexes, the position of the ratchet lock allows forward movement of the disk more easily than reverse movement. This  
20 reduces the force needed for normal forward indexing or rotation, and further guards against reverse indexing.

[0098] Referring to Figure 13, the inhaler is preferably designed to provide fail-safe drug availability to the user. If the actuator is moved from the home or stored

position AA in Figure 44 to only an intermediate position, near or at position BB in Figure 45, and is then returned to the home position AA before the blister is sheared open (i.e., with the seal layer still intact), no advancing occurs. In this case, the tooth 210 and the finger 208 of the actuator ride up and over the guide 174. The unopened  
5 and still sealed blister then remains in place in the blister opening position. This is achieved via the relative positions of the features on the actuator, the guide, and the dobber. On the other hand, if the actuator is moved far enough to begin shearing open a blister, so that the blister is no longer sealed, then the tooth 210 will have cleared the end of the guide 174, and it will move down under the guide and advance the blister  
10 disk to the next blister, as the actuator is returned to the home position. This largely prevents inhalation of a dose of powder which may have been exposed to the environment long enough to affect the powder characteristics, by e.g., causing particle size growth, caking, clumping, etc.

[0099] With the inhaler as shown in Figure 44, the dose windows 194 in the  
15 retainer 114, 180 in the base plate 102, and the first window 224 in the actuator 108 are aligned. Hence, the numbered blister aligned with the windows is visible. The user then can view how many doses remain on the blister disk. With the actuator in position CC as shown in Figure 46, the numbered blister is again visible, with the second window 222 of the actuator aligned with the other windows. This provides visual  
20 confirmation to the user that the actuator forward movement is complete. When the actuator is in an intermediate position, as shown in Figure 45, the arrows 226 are visible in the window 194. This provides a visual indication that the actuator should be further

moved to the inhale position CC. The arrows partially blocks the dose number marked on the blister aligned in the windows.

[00100] The blister disk 105, in the embodiment shown, has space for up to 16 blisters. After all of the blisters have been opened and used, the blister disk tray  
5 assembly 104 is replaced. The tray retainer 106 is opened, as shown in Figure 41. The tray assembly 104 is then pulled back out away from the inhaler 100, and a new tray assembly 104 is installed, as described above. As the actuator 108 must be at or near the home position AA to open or release the retainer 114, the dobber is automatically in its home or up position when the tray assembly 104 is changed. This prevents inadvertent  
10 opening of a blister when the new tray assembly is installed.

[00101] Referring to Figures 13 and 32, the blister hood 234 is vertically above the blister 356 in the blister opening position 309. Consequently, the powder in the blister 356 flows up, against the force of gravity, and is entrained in the air flow generated by the users inhalation. Test results show that about 10% of the powder  
15 remains in the up-facing blister. However, the fine particle fraction of the dose delivered remains high. This apparently occurs because the active drug particles which are more loosely attached to the carrier particles, flow out first from the upward facing blister 356. The residual powder remaining in the blister after the dose is delivered is of lower respirability because it includes larger particle sizes. Hence, fewer non-respirable  
20 particles move out of the blister 352 and into the dispersion engine 164, and fewer of them are inhaled by the user.

[00102] All surfaces in the inhaler that come into contact with the drug powder are part of a single subassembly, i.e., the dispersion engine including the hood and engine tube. This provides flexibility for use of the inhaler with different drugs.

[00103] The design shown in Figures 13 and 32 also acts as a multidose deterrent.

- 5 When the blister 356 is sheared open, the powder 358 does not fall out of the blister. Rather, the powder remains in the blister until inhalation. Accordingly, if a blister is opened, but the user does not inhale and then subsequently moves the actuator again, the blister 356 is simply reclosed (the tab pivots closed, although the clear layer is severed), with the powder 358 remaining therein, and a new blister is brought into alignment to  
10 the blister opening position 309.

[00104] In a single use embodiment, the blister disk and/or tray or tray assembly may be part of or effectively permanently attached to the inhaler. The inhaler would then be discarded after all doses on the blister disk are used. In this embodiment, the retainer or latch 114 and tray features may be omitted.

## CLAIMS

1. An inhaler for providing multiple doses of a pharmaceutical from blisters on a blister disk, comprising:
- a base;
- 5 an actuator pivotable on the base from a first position to a second position ;
- a dobber engaged with the actuator, and with the actuator driving the dobber to open a blister on the blister disk, as the actuator moves from the first position to the second position.
- 10 2. The inhaler of claim 1 wherein the actuator is on a first side of the base, and a second side of the base includes a tray position for holding a blister tray.
3. The inhaler of claim 1 further comprising a tray retainer on the base, with the tray retainer moveable between open and closed positions, and with the actuator moveable to a position at least partially overlying the tray retainer, when the tray
- 15 retainer is in the closed position.
4. The inhaler of claim 1 wherein a ramp on the actuator is engaged with the dobber and the actuator is pivotable about a first axis and the dobber is pivotable about a second axis perpendicular to the first axis.
5. The inhaler of claim 1 further including an advancing finger on the
- 20 actuator extendible through an opening in the base.

6. An inhaler for providing individual doses of a pharmaceutical from blisters on a blister disk in a tray, comprising:
- a base plate;
  - a tray retainer on the base plate, with the tray retainer having a tray
- 5 holding section;
- an actuator on the base plate for opening blisters on the blister disk;
  - with the tray retainer moveable from a closed position, wherein the tray
- holding section of the tray retainer secures the tray onto the base plate, to an open position, wherein the tray holding section is spaced apart from the base plate, to allow
- 10 removal and replacement of the tray.
7. The inhaler of claim 6 where the tray retainer is pivotably attached to the base plate.
8. The inhaler of claim 7 further including a mouthpiece frame on a first side of the base plate, and with the tray holding section of the tray retainer holding the
- 15 tray into engagement with the mouthpiece frame, when the tray retainer is in the closed position.
9. The inhaler of claim 7 wherein the actuator is pivotable from a first position away from the tray retainer, to a second position overlying the tray retainer, when the tray retainer is in the closed position.

10. The inhaler of claim 7 wherein the tray holding section has a radius of curvature generally matching the radius of curvature of a back section of the blister tray.

11. The inhaler of claim 7 wherein the tray retainer includes a pivot arm  
5 pivotably attached to the second side of the base plate, and with the tray holding section joined to the pivot arm.

12. An inhaler for delivering individual doses of a dry powder pharmaceutical from blister containers on a blister disk, comprising:  
an inhaler housing having top and bottom surfaces;  
10 means for holding the blister disk on or in the inhaler housing, with the blister containers in an up facing position;  
means for incrementally advancing the blister containers on the blister disk to a blister opening position in the housing;  
means for opening up a top surface of the blister containers, at the blister  
15 opening position; and  
a blister hood over the blister opening position, for conducting powder drawn up and out of an open blister at the blister opening position, into a dispersion engine.

13. An inhaler for delivering individual doses of a dry powder  
20 pharmaceutical from blister containers on a blister disk, comprising:  
an inhaler housing;

a blister opening position in the inhaler housing;  
a powder dispersion engine in the housing;  
a blister hood over the blister opening position; and  
a powder pathway connecting from the blister hood into the powder  
5 dispersion engine.

14. The inhaler of claim 13 with the powder dispersion engine including an engine tube extending into a mouthpiece.

15. The inhaler of claim 14 further including ribs extending radially inwardly into the engine tube.

10 16. The inhaler of claim 13 further including an actuator on the housing, and a dobber at the blister opening position and engaged with the actuator.

17. The inhaler of claim 16 wherein the dobber is at least partially over the blister hood, with movement of the actuator driving the dobber to shear open a blister on the blister disk, and with the dobber also pressing the blister hood down over the open  
15 blister.

18. The inhaler of claim 13 further comprising a dust cap attached to the inhaler housing via a hinge oriented at an acute angle to the housing.

19. A method for operating a dry powder inhaler, comprising the steps of:  
installing a tray holding a blister disk onto or into the inhaler;

pivoting an actuator in a first direction about a first axis to drive a dobber to pivot about a second axis, generally perpendicular to the first axis, causing the dobber to shear open a blister on the blister disk;

conducting powder up and out of the open blister and into a dispersion  
5 engine, via air flow;

dispersing the powder in the dispersion engine; and

pivoting the actuator in a second direction, opposite to the first direction,  
to advance the blister disk in the tray.

20. A blister disk tray assembly, comprising:

10 a bottom wall;

a curved side wall joined to the bottom wall;

a blister disk mounting hub on the bottom wall;

a blister disk pivotably supported on the mounting hub; and

a lockout ratchet on the bottom wall biased into a first position wherein  
15 the lockout ratchet engages the blister disk and prevents pivotal movement of the blister disk, and with the lockout ratchet temporarily displaceable into a second position disengaged from the blister disk, to allow the blister disk to pivot on the mounting hub.

21. The tray assembly of claim 20 further comprising a circumferential base wall on the bottom wall, substantially surrounding the blister disk mounting hub.

22. The tray assembly of claim 20 further including a front wall joined to the bottom wall and side wall, and with the side wall having a radius of curvature greater than the front wall.

23. The tray assembly of claim 20 further having a front wall joined to the side wall and to the bottom wall, and a return spring attached to the front wall.

24. The tray assembly of claim 20 further including a blister opening position formed adjacent to the sidewall, and including a return spring at the blister opening position.

25. The tray assembly of claim 20 with the blister disk having a plurality of tabs radially spaced apart and further comprising a blister tab base wall attached to the bottom wall and aligned under the tabs of the blister disk.

26. The tray assembly of claim 20 wherein the bottom wall has an outside surface including a plurality of feet for supporting the tray assembly in a horizontal plane without rocking..

27. An inhaler for providing individual doses of a pharmaceutical from blisters on a blister disk in a tray, comprising:

a base having a base dose window;

a tray retainer pivotably attached to the base plate, with the tray retainer having a retainer dose window;

an actuator pivotably attached to the base, with the actuator having an actuator dose window;

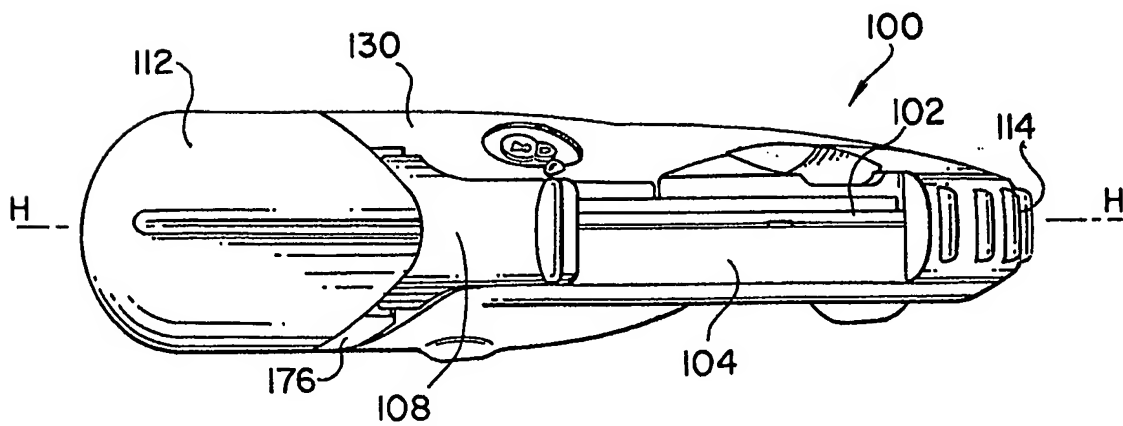
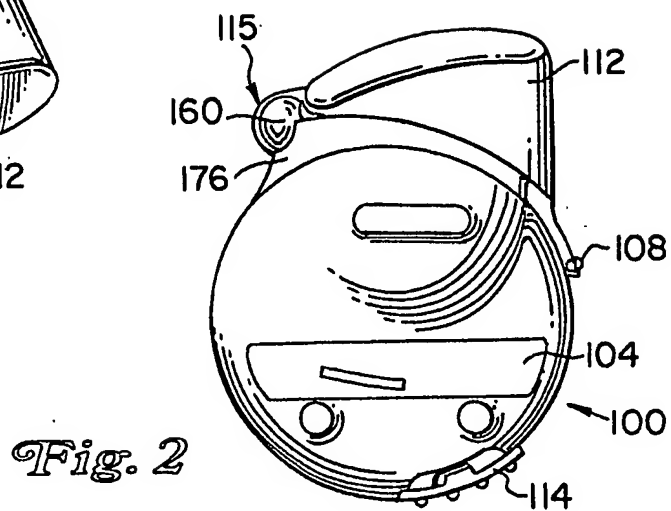
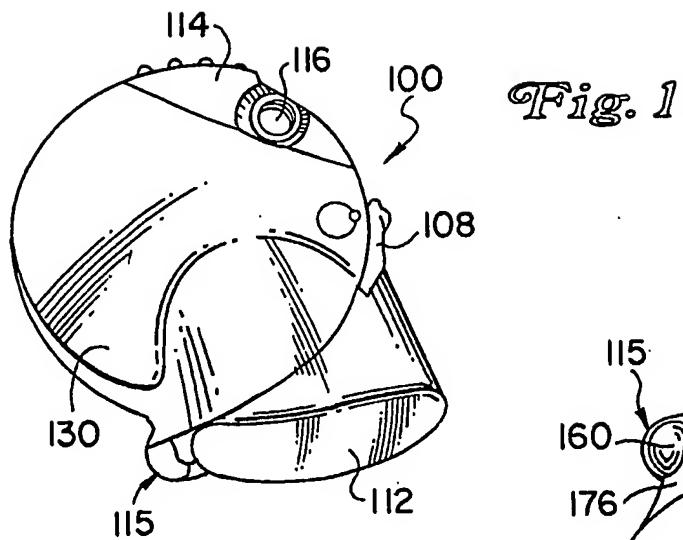
with the tray retainer moveable from a first position to an second position, and the actuator is moveable from a third position to a fourth position, and  
5 with the base dose window, the retainer dose window, and the actuator dose window aligned with each other when the tray retainer is in the first position, and the actuator is in third position or in the fourth position.

28. The inhaler of claim 27 wherein the base has a first side and a second side, and with tray retainer and the actuator both on the first side of the base.

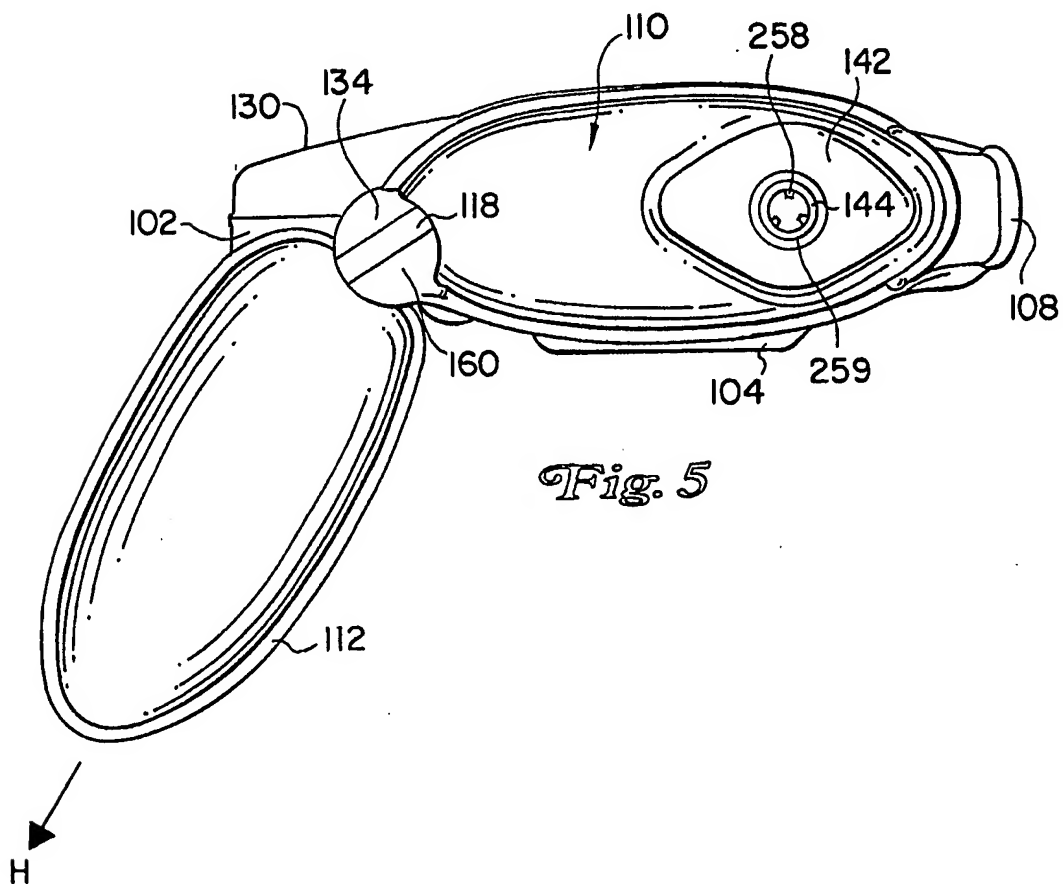
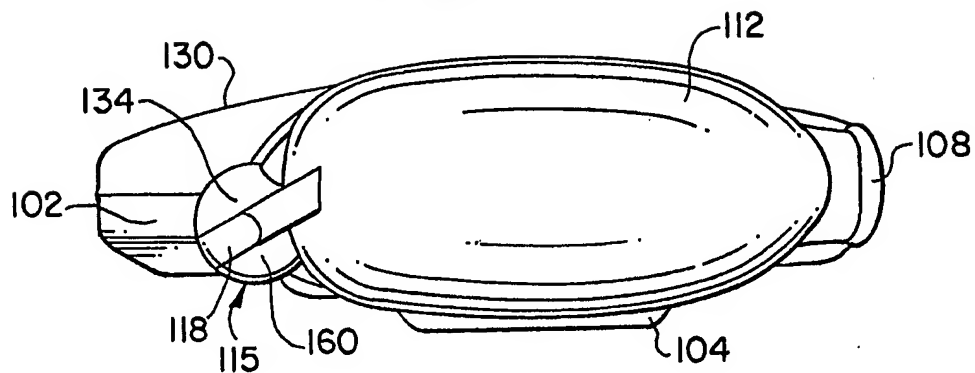
10 29. The inhaler of claim 27 wherein the actuator includes two spaced apart actuator dose windows.

30. The inhaler of claim 27 wherein the base has a first side and second side, and further comprising a top cover covering a first section of the first side of the base,  
15 and with the tray retainer covering a second section of the first side of the base.

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*Fig. 4*

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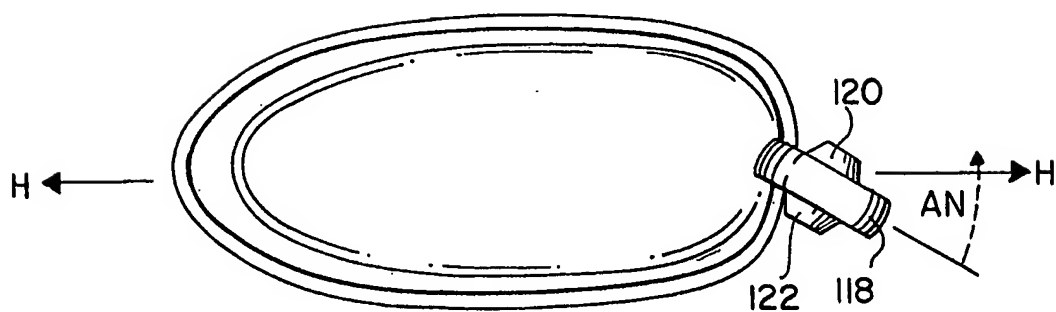
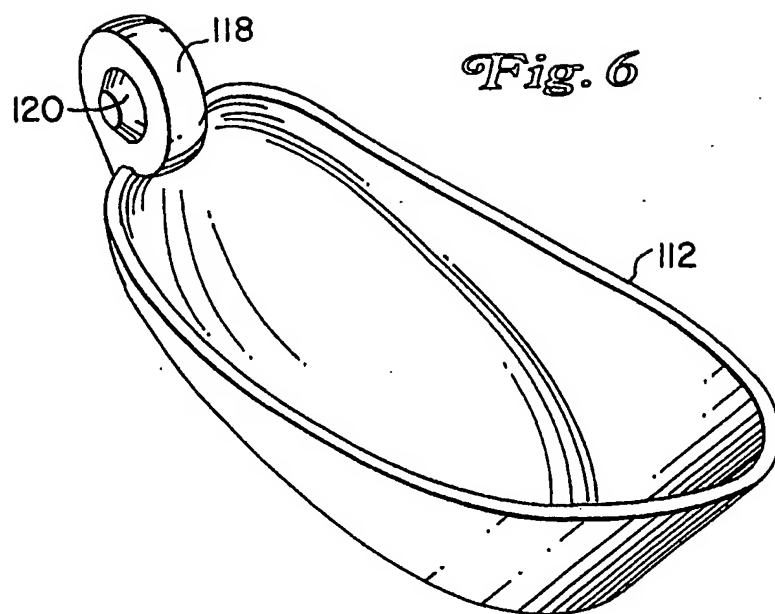
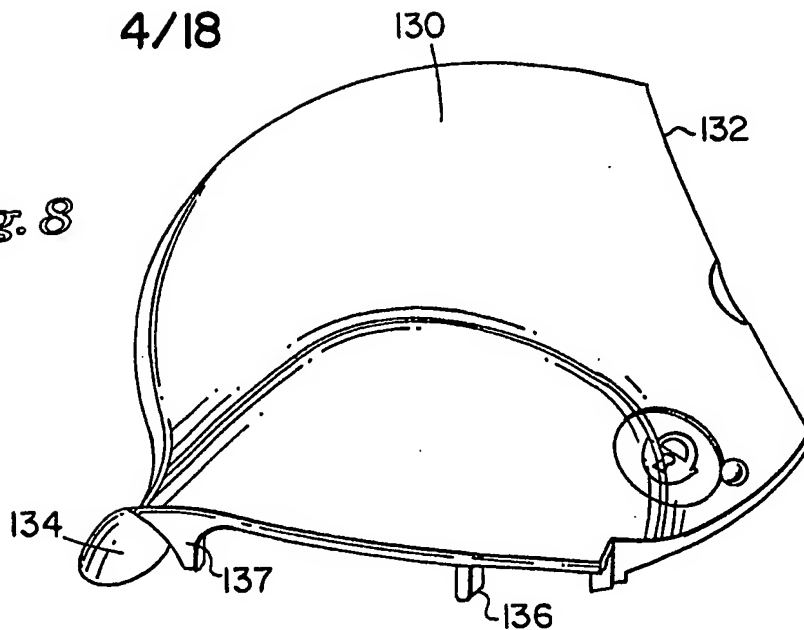


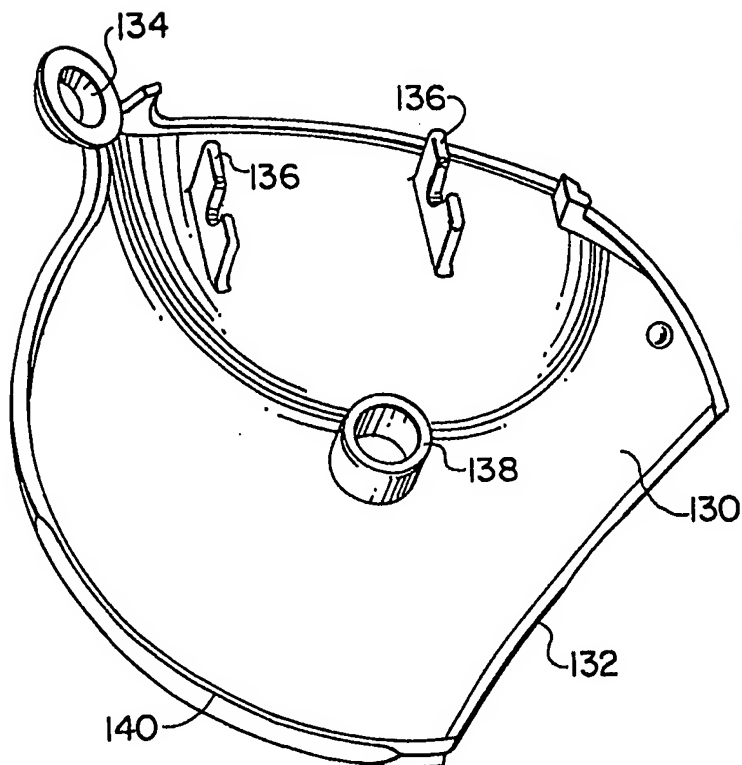
Fig. 7

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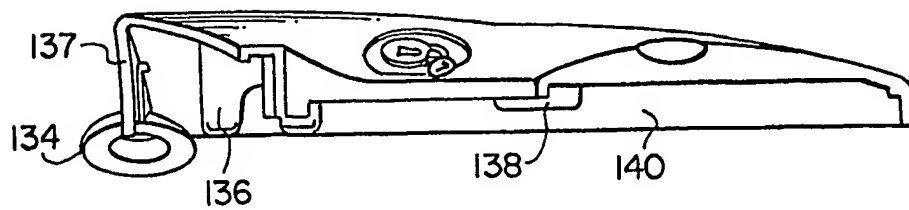
*Fig. 8*



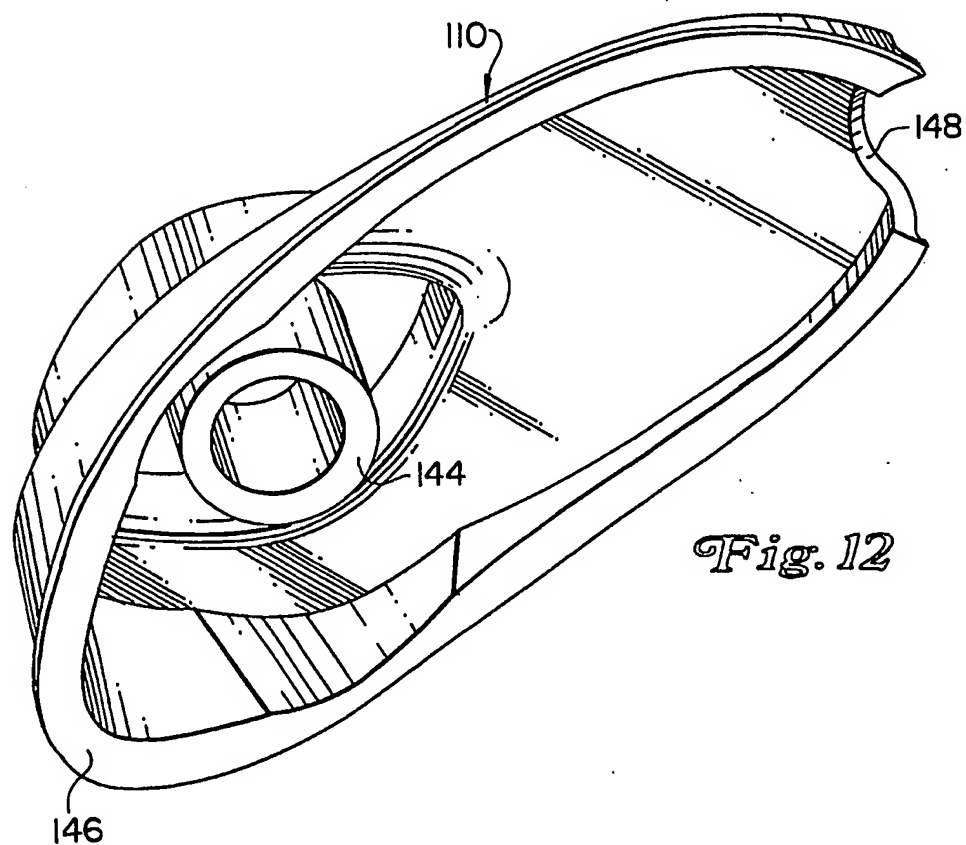
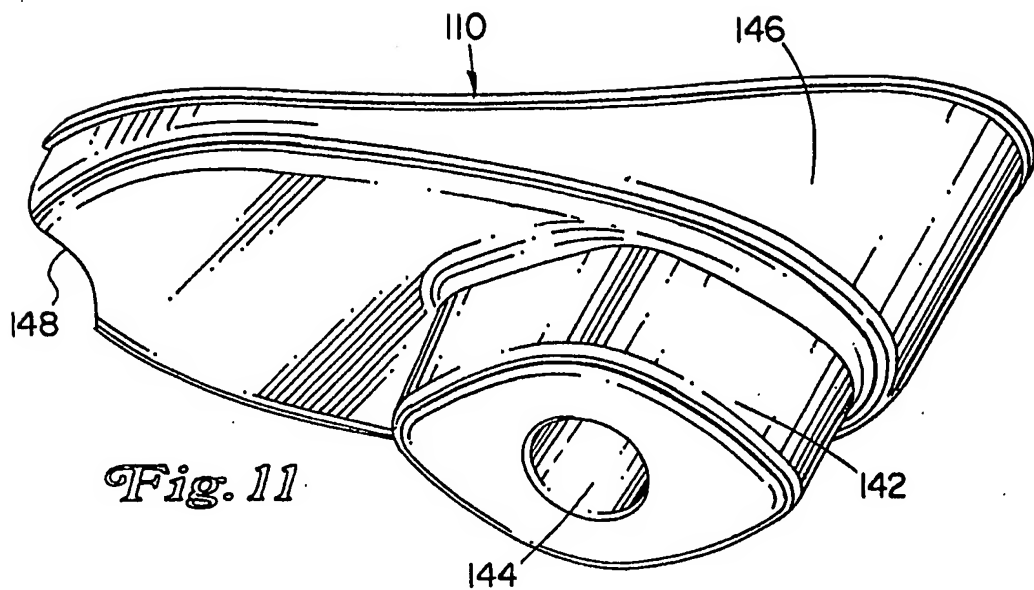
*Fig. 9*



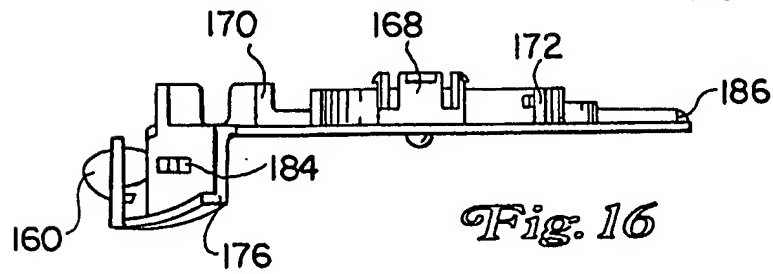
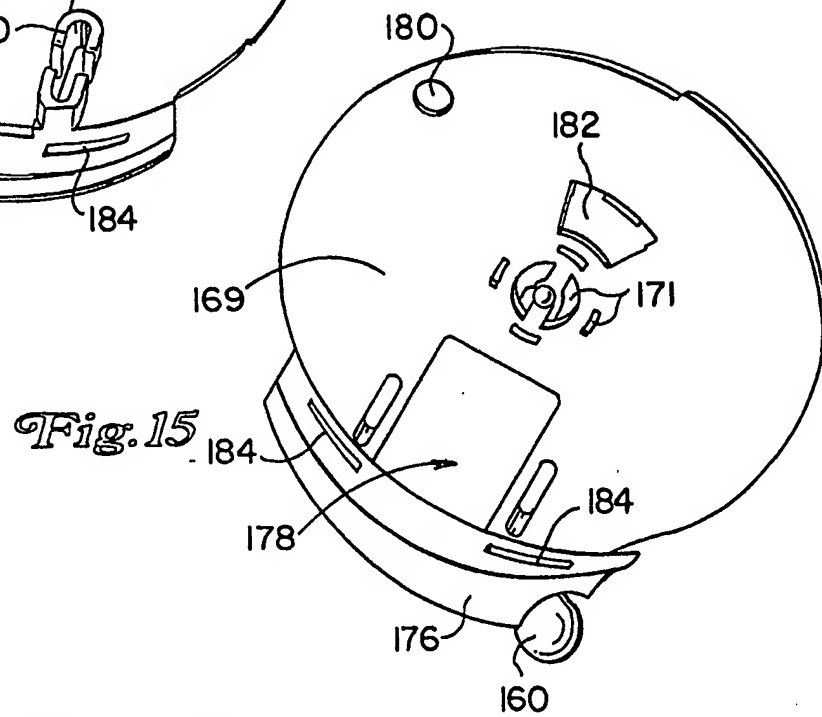
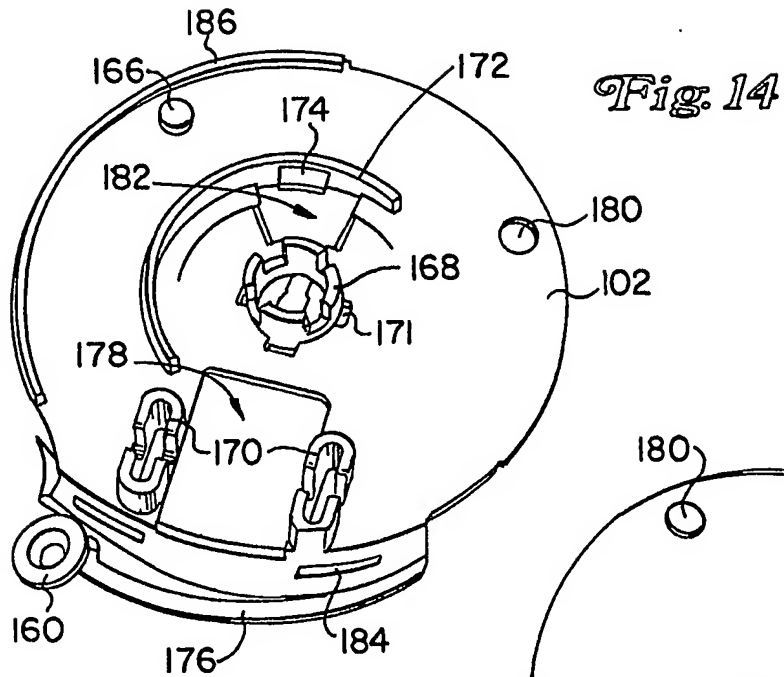
*Fig. 10*



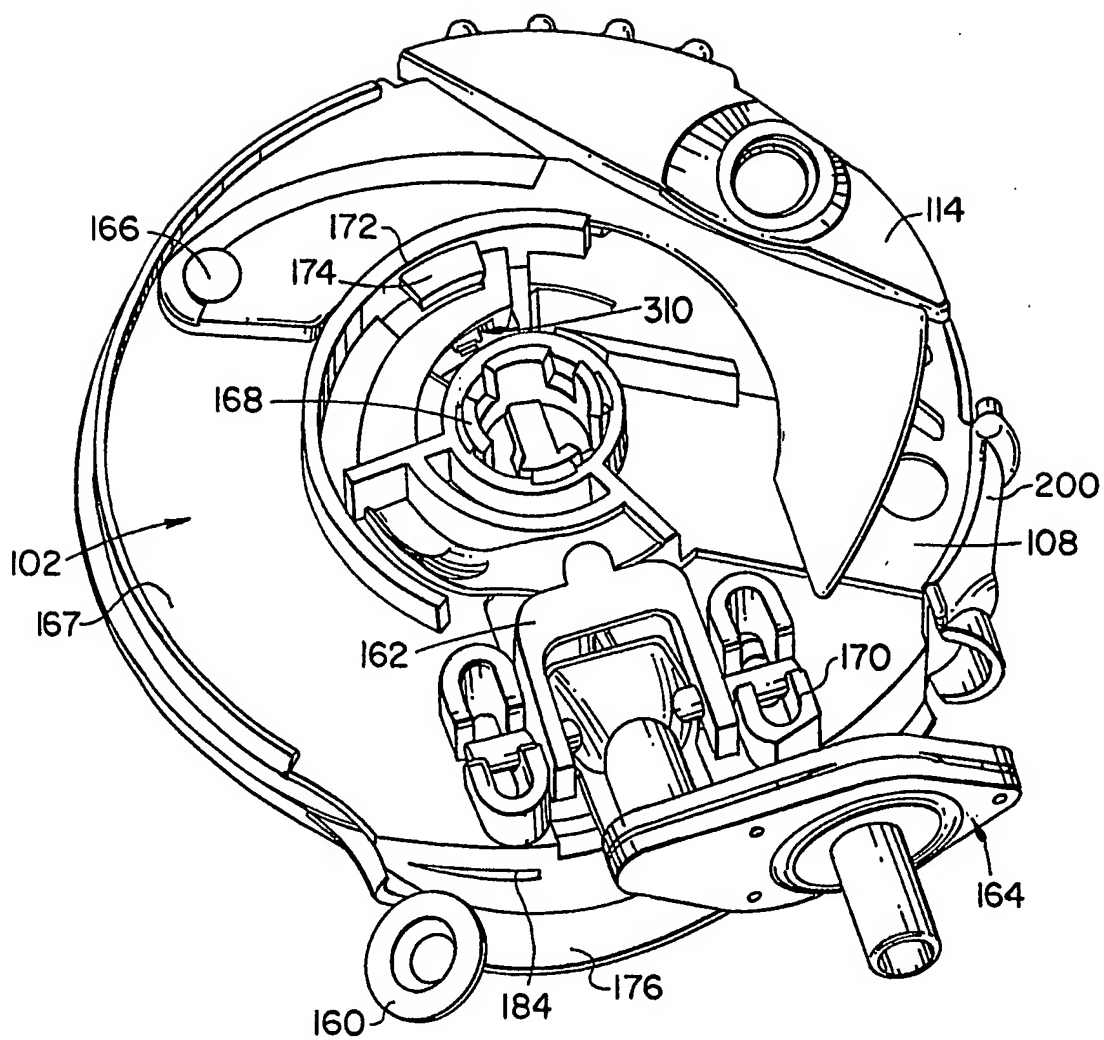
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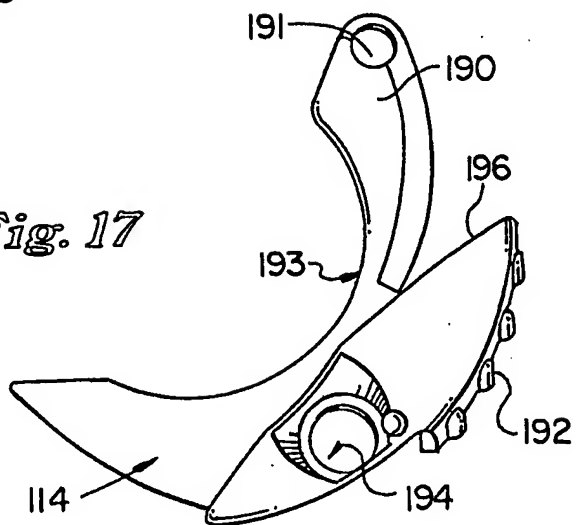


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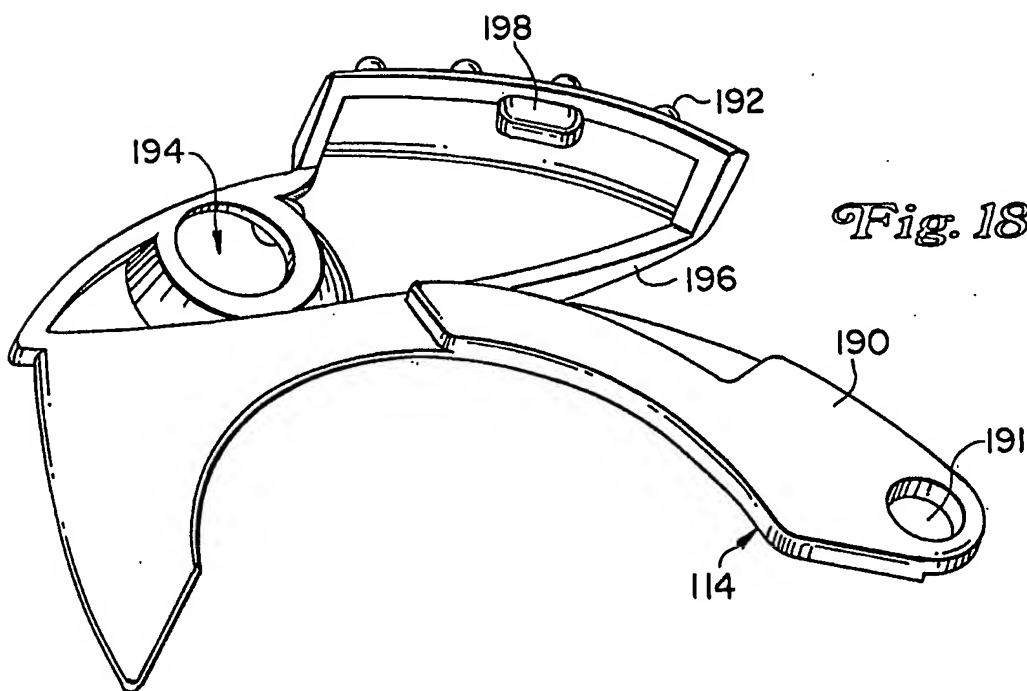
*Fig. 13*

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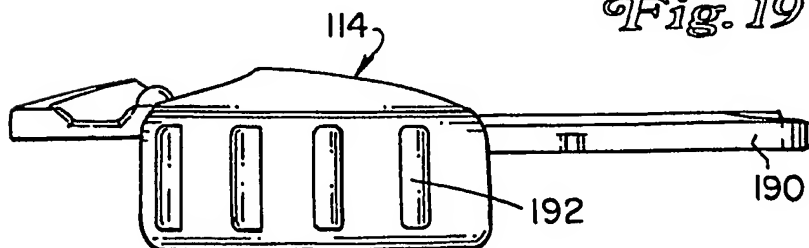
*Fig. 17*



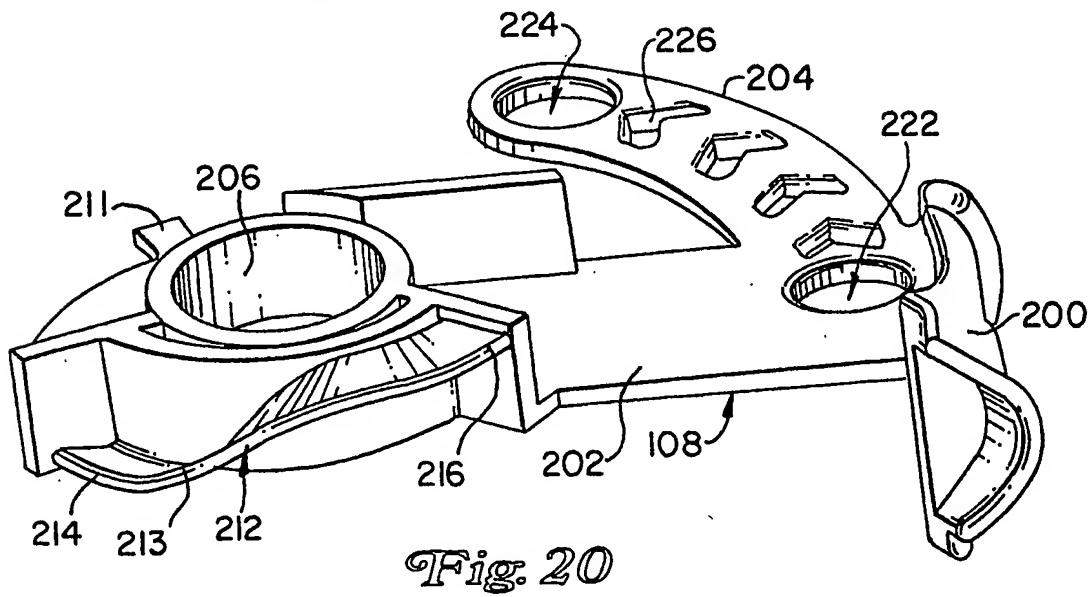
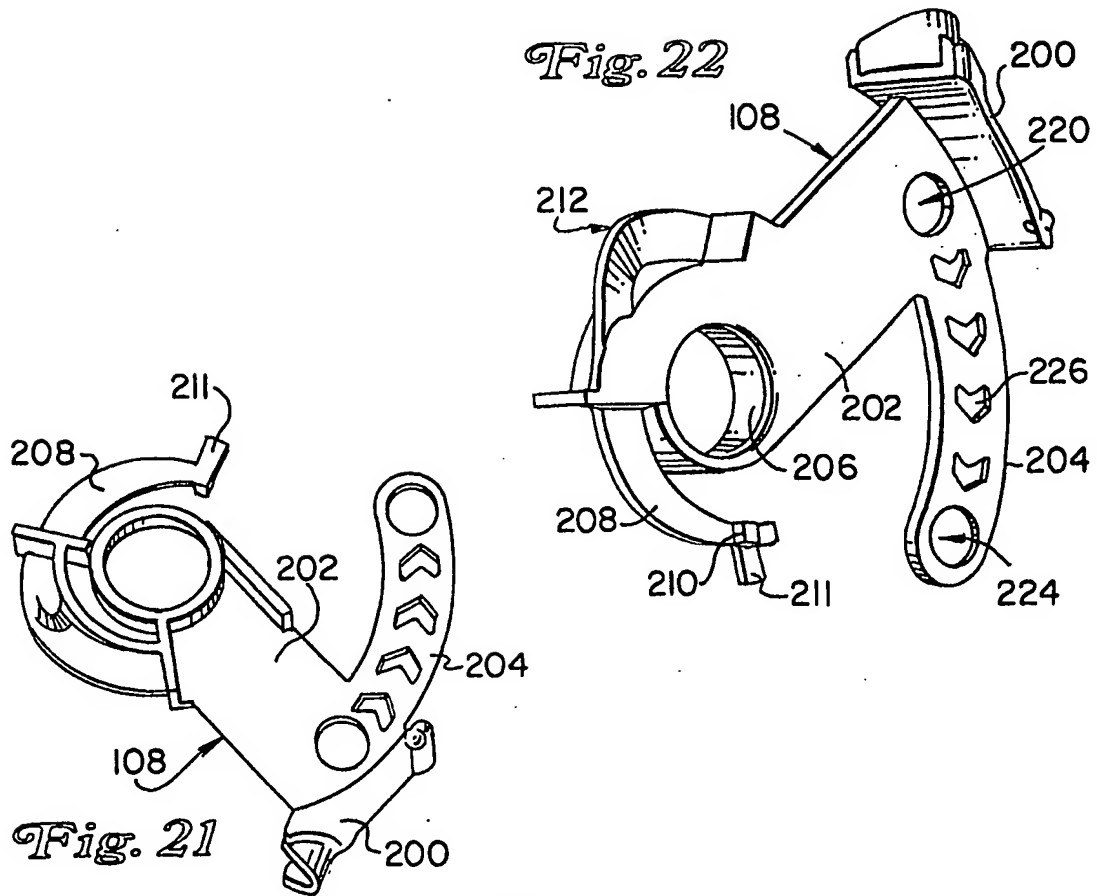
*Fig. 18*



*Fig. 19*

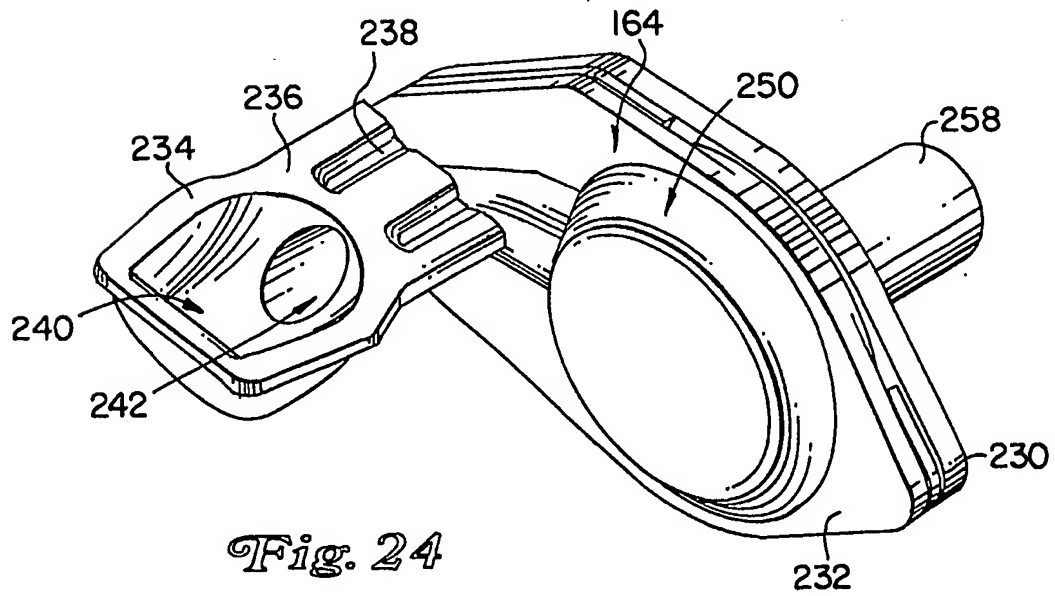
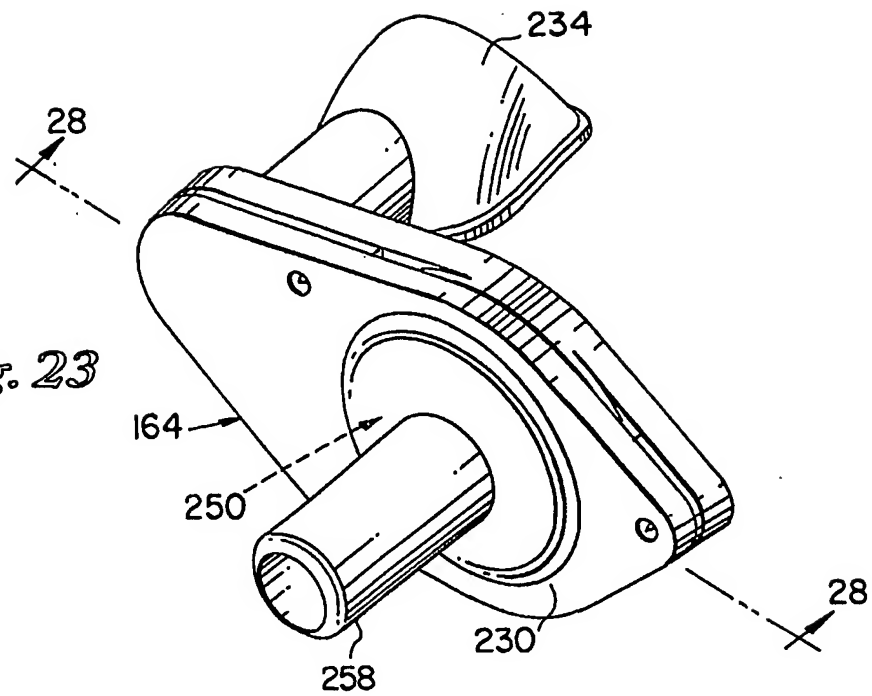


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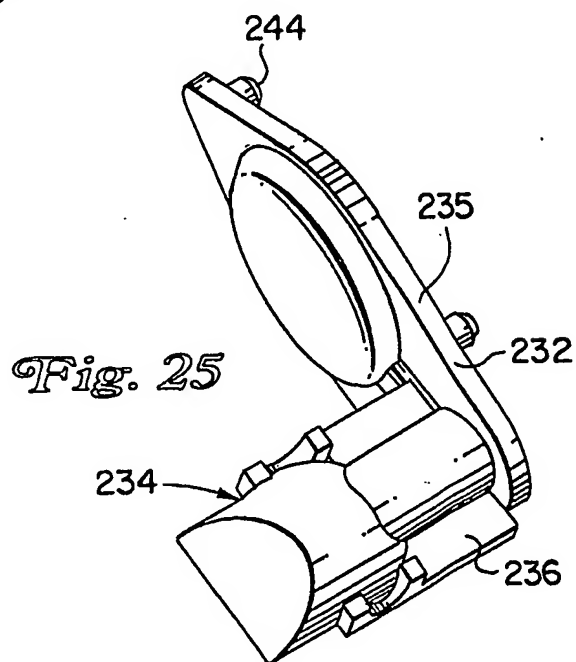
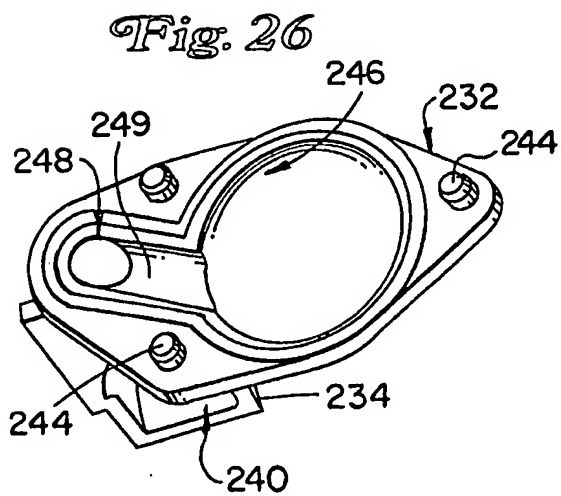
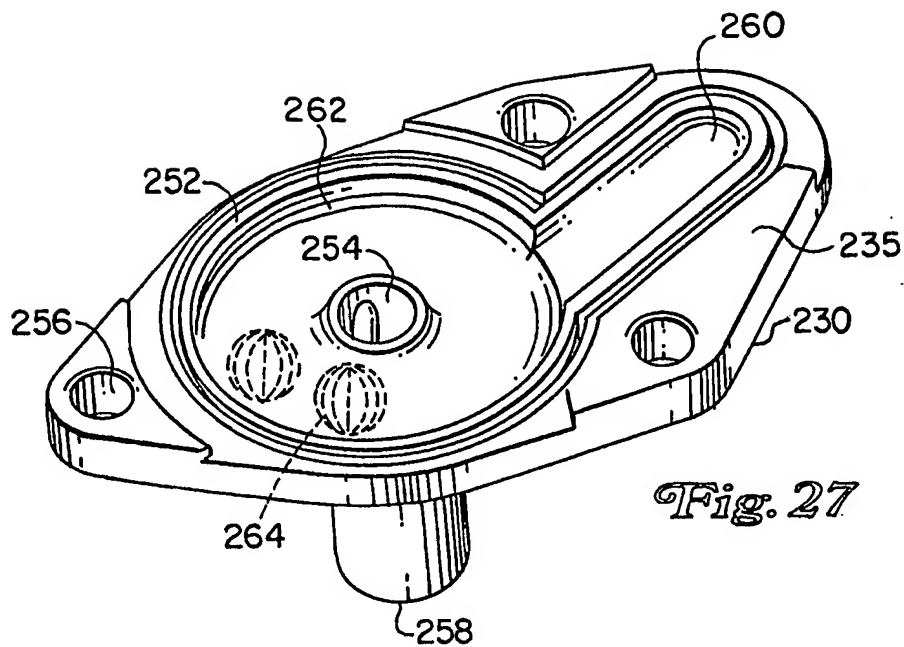
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*Fig. 23*

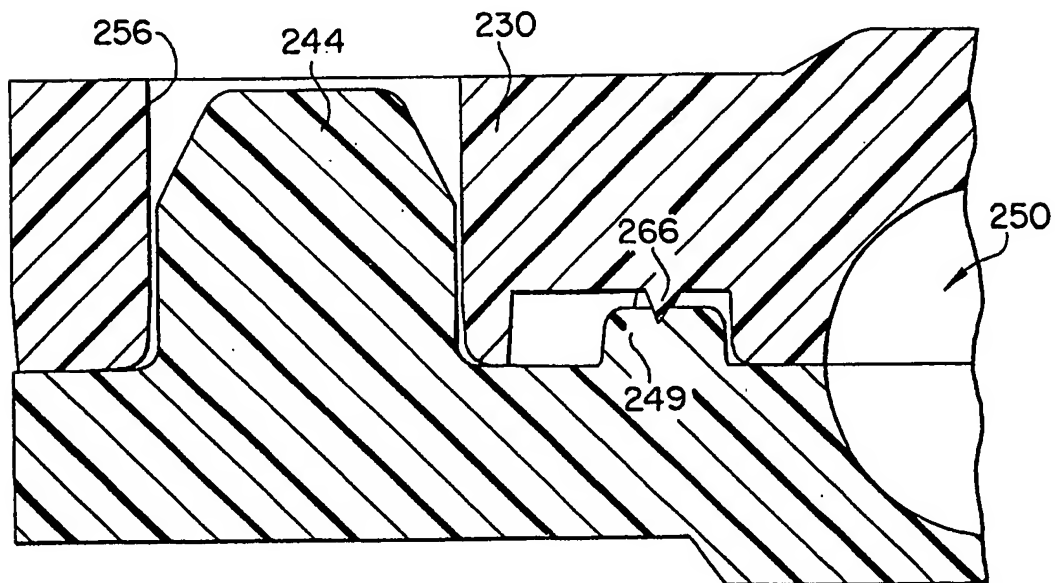
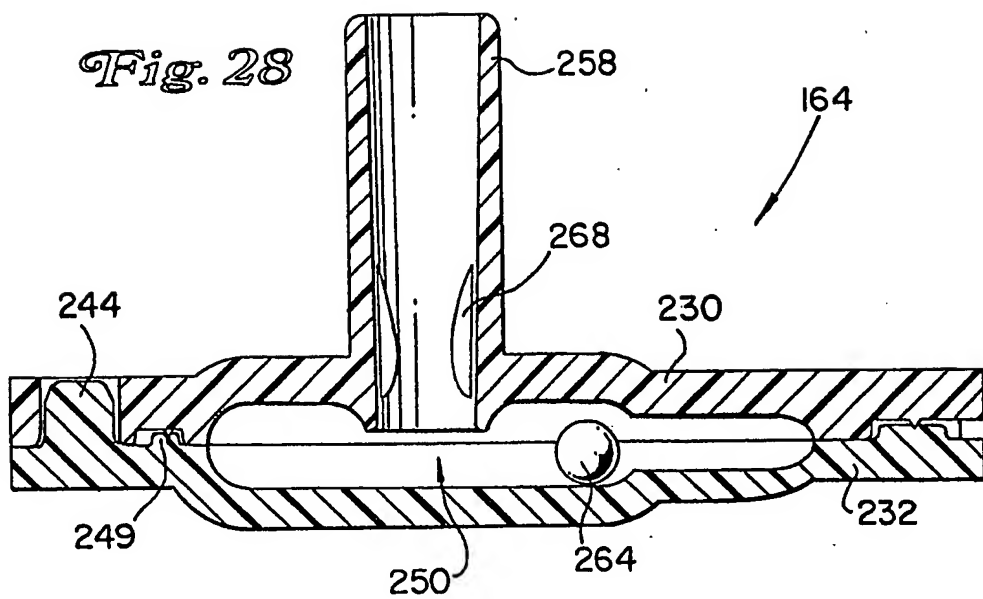


*Fig. 24*

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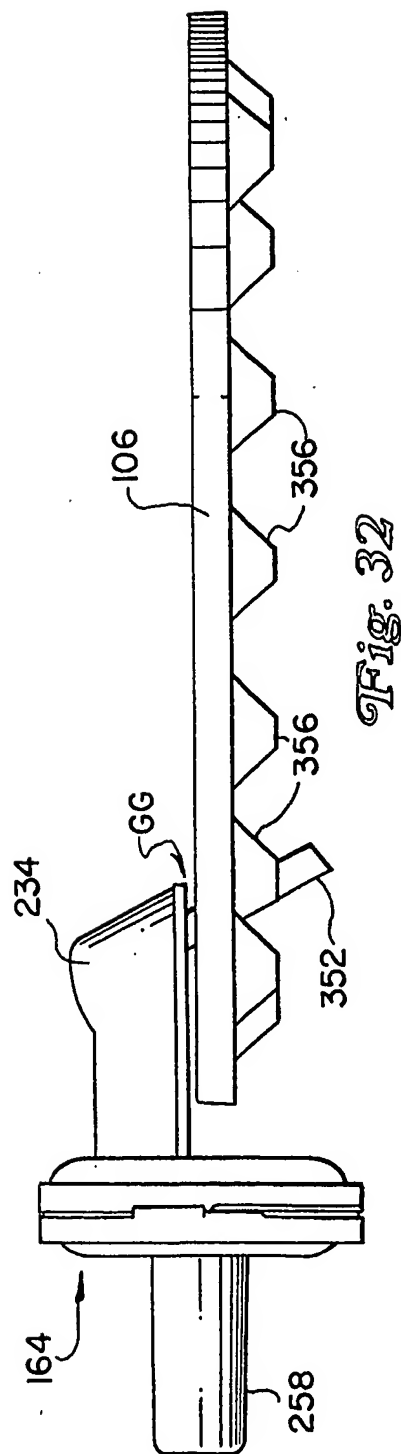
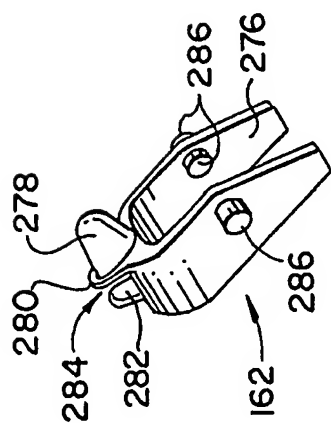
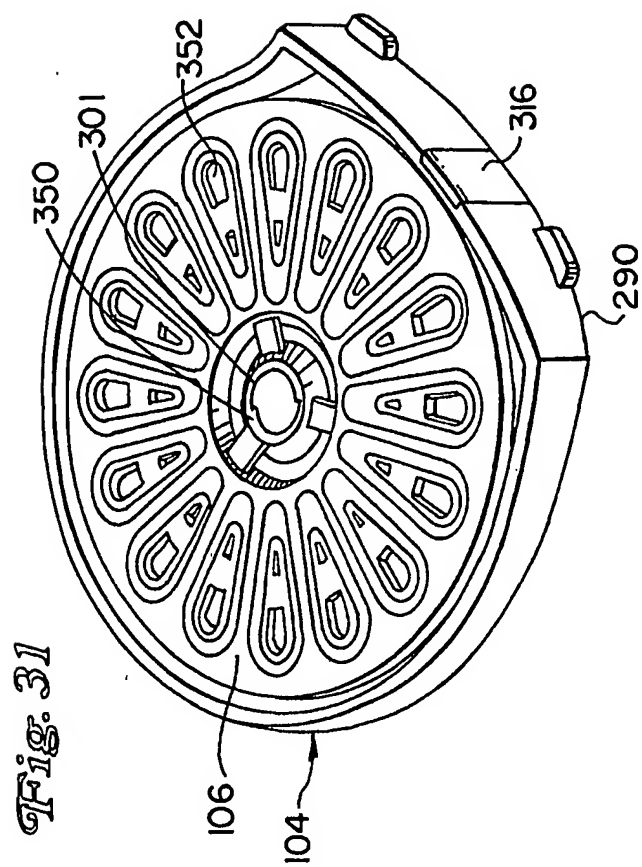


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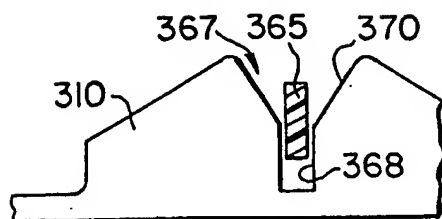


*Fig. 29*

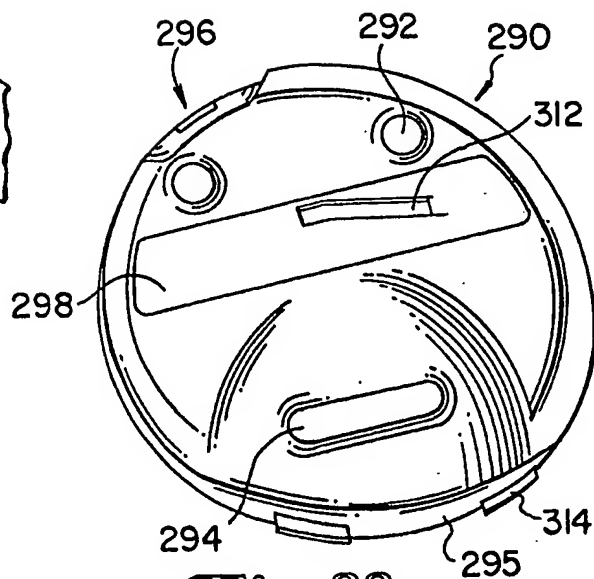
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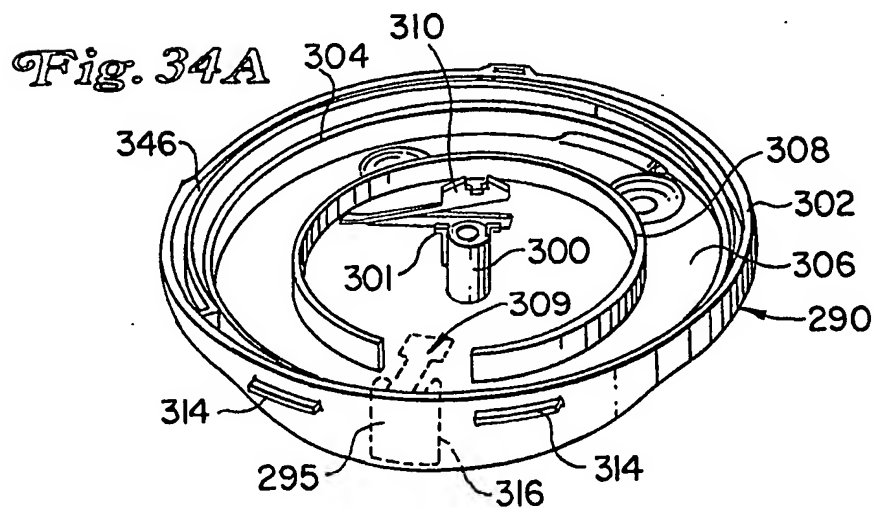
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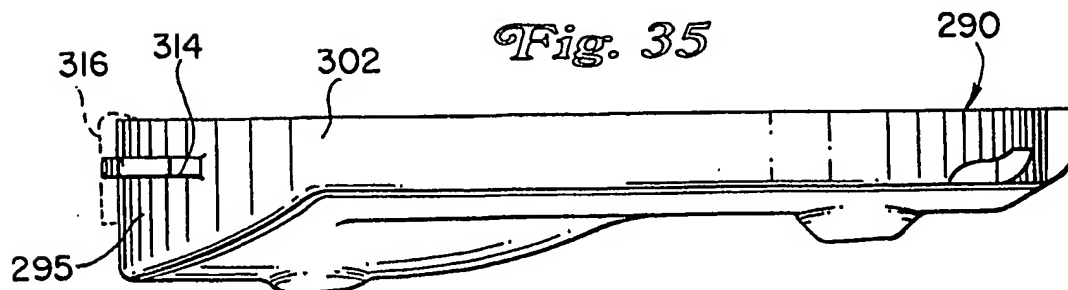
*Fig. 34B*



*Fig. 33*

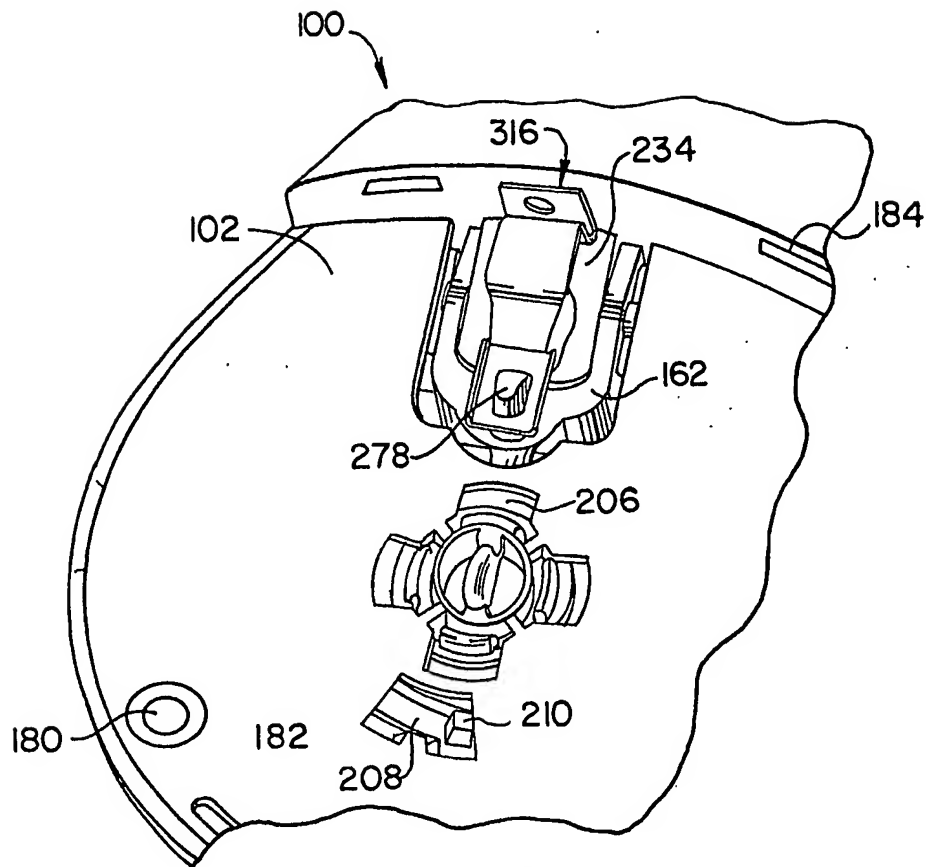


*Fig. 34A*

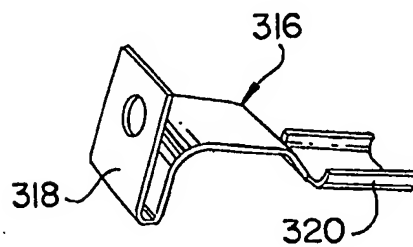


*Fig. 35*

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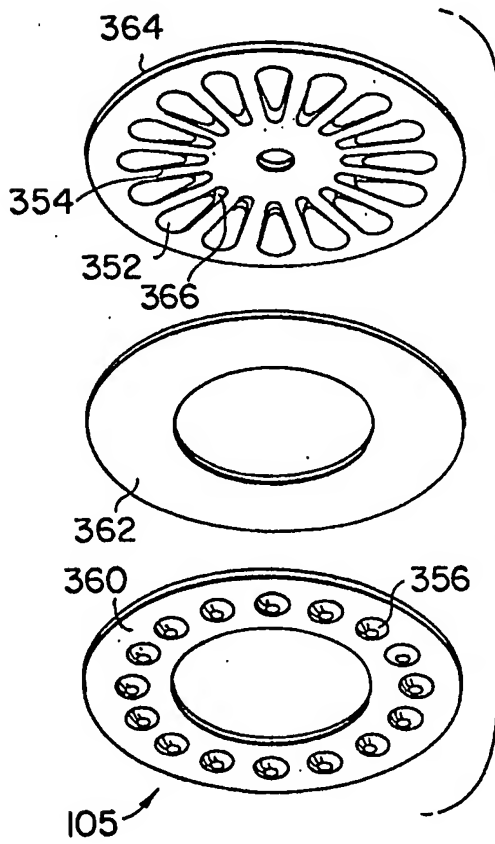
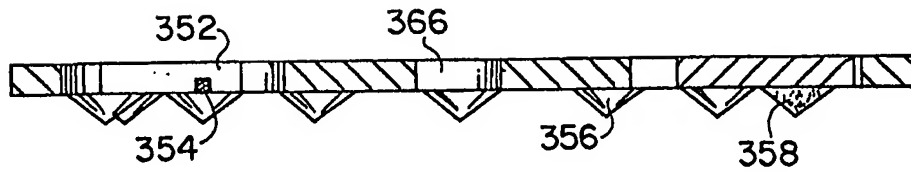
*Fig. 37*



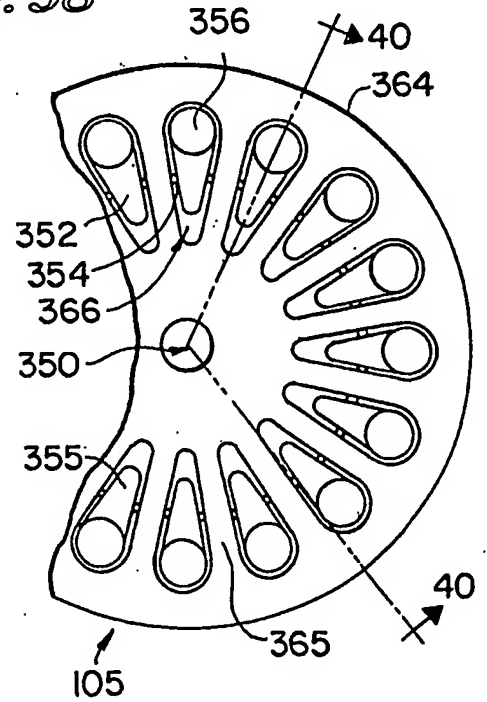
*Fig. 36*

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*Fig. 40*

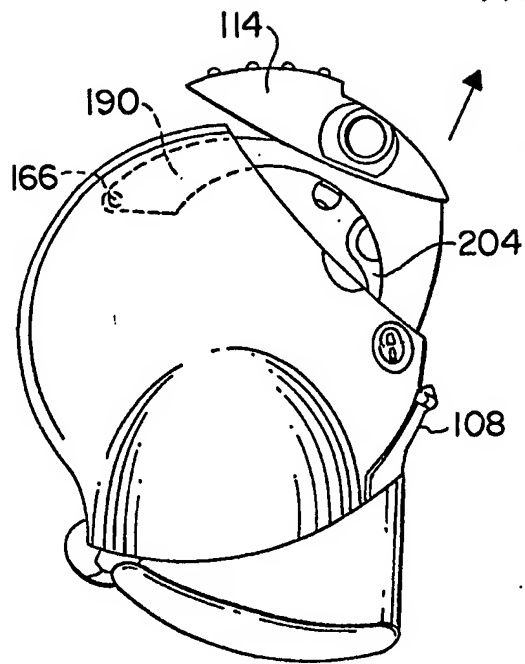


*Fig. 38*

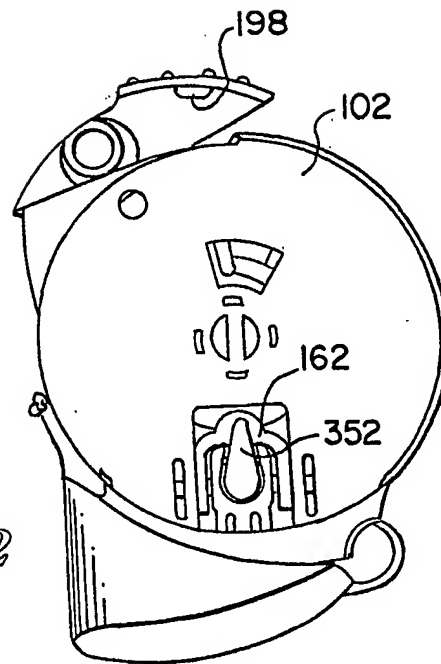


*Fig. 39*

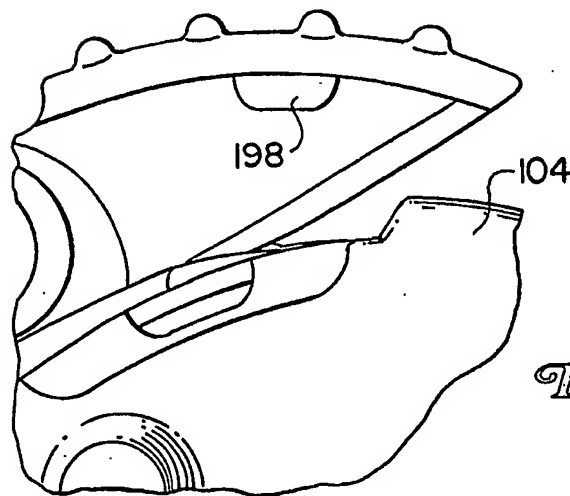
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*Fig. 41*

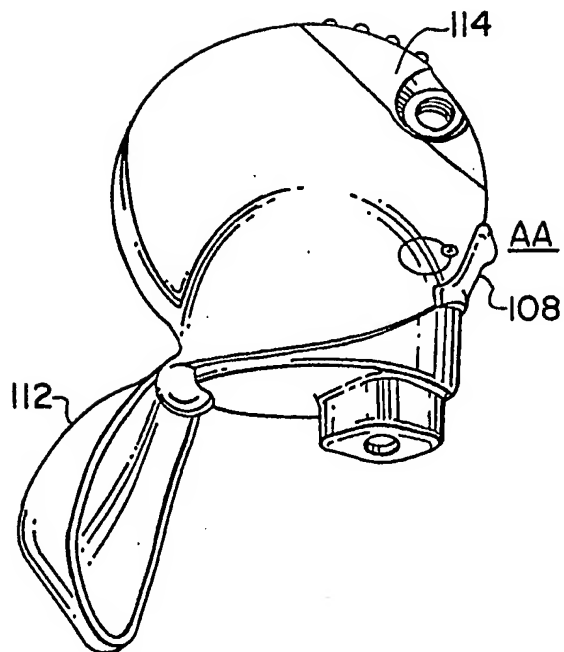


*Fig. 42*

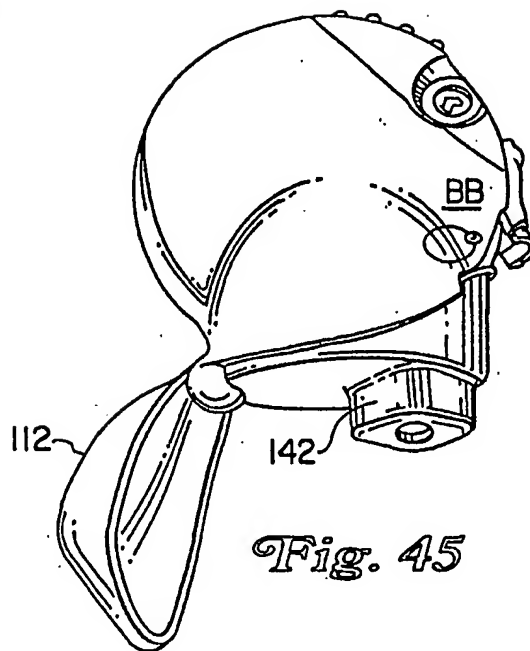


*Fig. 43*

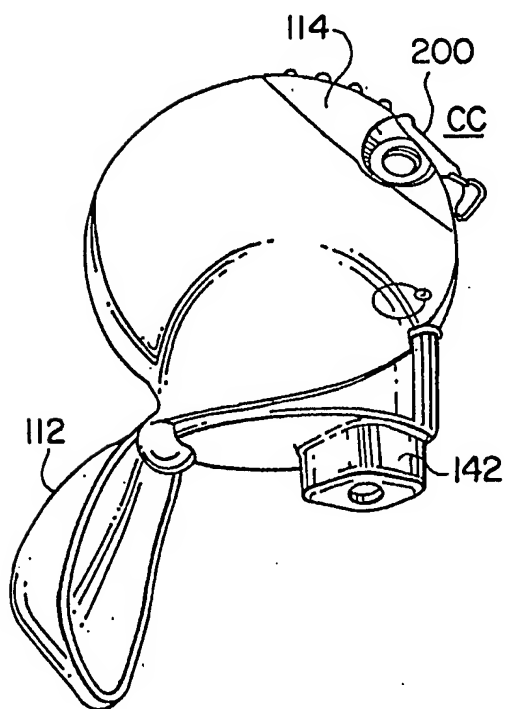
18/18



*Fig. 44*



*Fig. 45*



*Fig. 46*

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/07929

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61M 15/00, 16/10; B05D 7/14; B65D 83/06

US CL : 128/203.15

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/203.12, 203.15; 604/58; 222/636

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Dry powder inhaler, dobber, ratchet, blister disk

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,388,572 A (Mulhauser et al.) 14 February 1995, see figure 10 and supporting text.	1-30
Y	US 5,921,237 A (Eisele et al) 13 July 1999, see figure 5 and supporting text.	1-30
Y	US 4,841,964 A (Hurka et al.) 27 June 1989, dispersion engine see fig 2 and supporting text.	13-19

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"B" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

13 MAY 2003

Date of mailing of the international search report

01 AUG 2003

 Name and mailing address of the ISA/US  
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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US03/07929

## BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-5, drawn to An inhaler using a dobber.

Group II, claim(s) 6-11 & 27-30, drawn to An Inhaler with a movable tray retainer.

Group III, claim(s) 12-19, drawn to An Inhaler with a blister hood.

Group IV, claim(s) 20-26, drawn to An Inhaler with a lockout ratchet.

The inventions listed as Groups I, II, III & IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They do not have a unity of special technical critical features, Grp I uses a dobber, Grp II uses a movable tray retainer, Grp III uses a blister hood and Grp IV uses a ratchet.